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Supreme Court, U.S.
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In The
Supreme Court of the United States

MEDRAD, INC.,

Petitioner,

v.

LIEBEL-FLARSHEIM COMPANY
and MALLINCKRODT, INC.,

Respondents.

**On Petition For Writ Of Certiorari
To The United States Court Of Appeals
For The Federal Circuit**

SUPPLEMENTAL APPENDIX

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US005456669A

United States Patent [19]

Neer et al.

[11] Patent Number: 5,456,669

[45] Date of Patent: Oct. 10, 1995

[54] **METHOD OF FRONT LOADING AN INJECTOR AND INJECTING FLUID INTO ANIMALS THEREWITH**

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[73] Assignee: **Liebel-Flarsheim Company**, Cincinnati, Ohio

[21] Appl. No.: **158,765**

[22] Filed: **Nov. 30, 1993**

Related U.S. Application Data

[62] Division of Ser. No. 881,782, May 11, 1992, Pat. No. 5,279,569, which is a division of Ser. No. 712,110, Jun. 7, 1991, Pat. No. 5,300,031.

[51] **Int. Cl.**[6] **A61M 37/00**

[52] **U.S. Cl.** **604/154**; 604/155

[58] **Field of Search** 604/131, 151, 604/152, 154, 155

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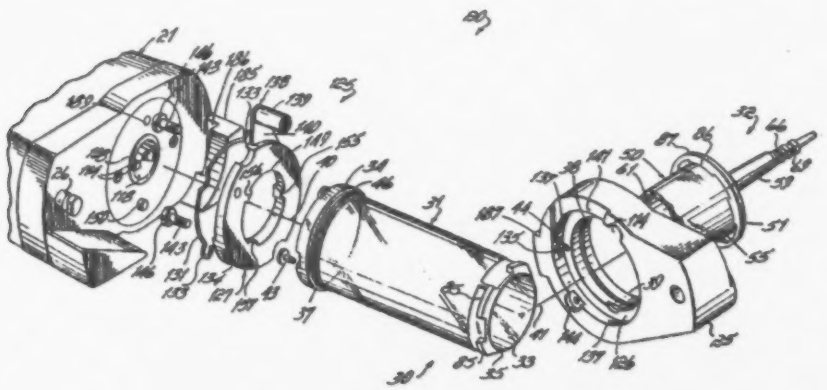
Primary Examiner—John G. Weiss
Attorney, Agent, or Firm—Wood, Herron & Evans

[57] **ABSTRACT**

An animal fluid injector, replaceable syringe and method of replacement of the syringe in the injector are provided in which the syringe is loadable and unloadable into and from the injector through the open front end of a pressure jacket of the injector, thereby permitting replacement without retraction of the syringe plunger drive or disconnection of the injection tubing. The syringe is provided with a pressure restraining front end, such as an integral or removable cap with structure such as threads that lock the syringe to the front end of the jacket by mating with threads on the jacket. A mechanism in the injector, which includes, for example, a key on cam ring operated by a lever with one hand of an operator, interacts with structure such asymmetrically spaced notches on the back end of the syringe to, for example, rotate the syringe and simultaneously translate or rotate a coupling on the syringe plunger into and out of engagement with the plunger drive in the injector.

37 Claims, 11 Drawing Sheets



Pat. 1

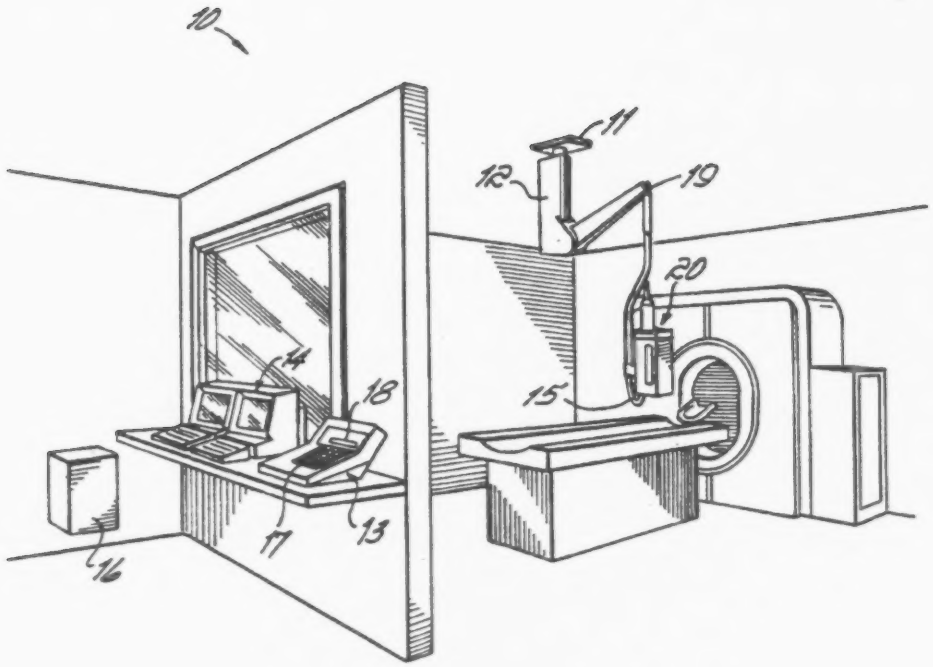


FIG. 1

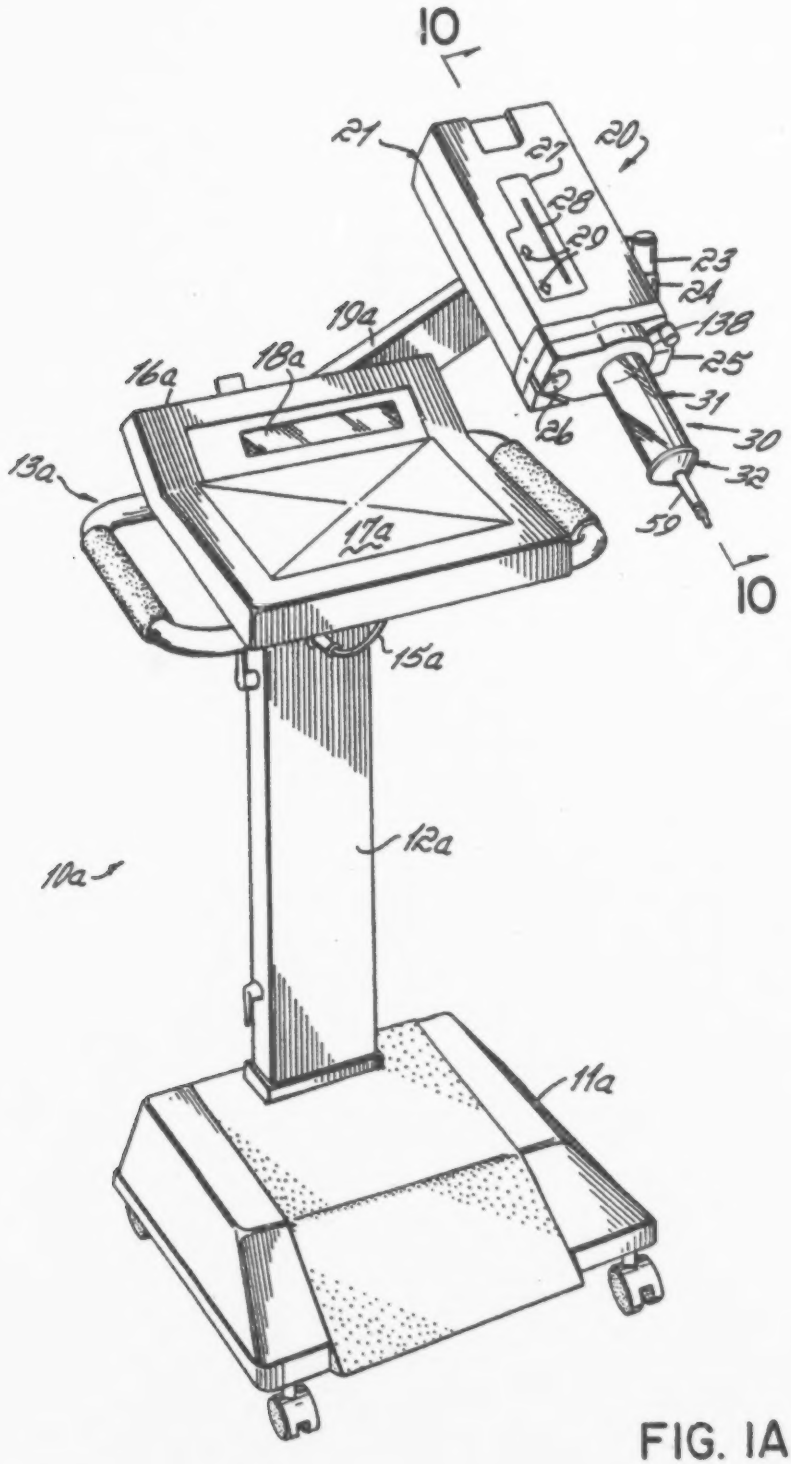

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FIG. 1A

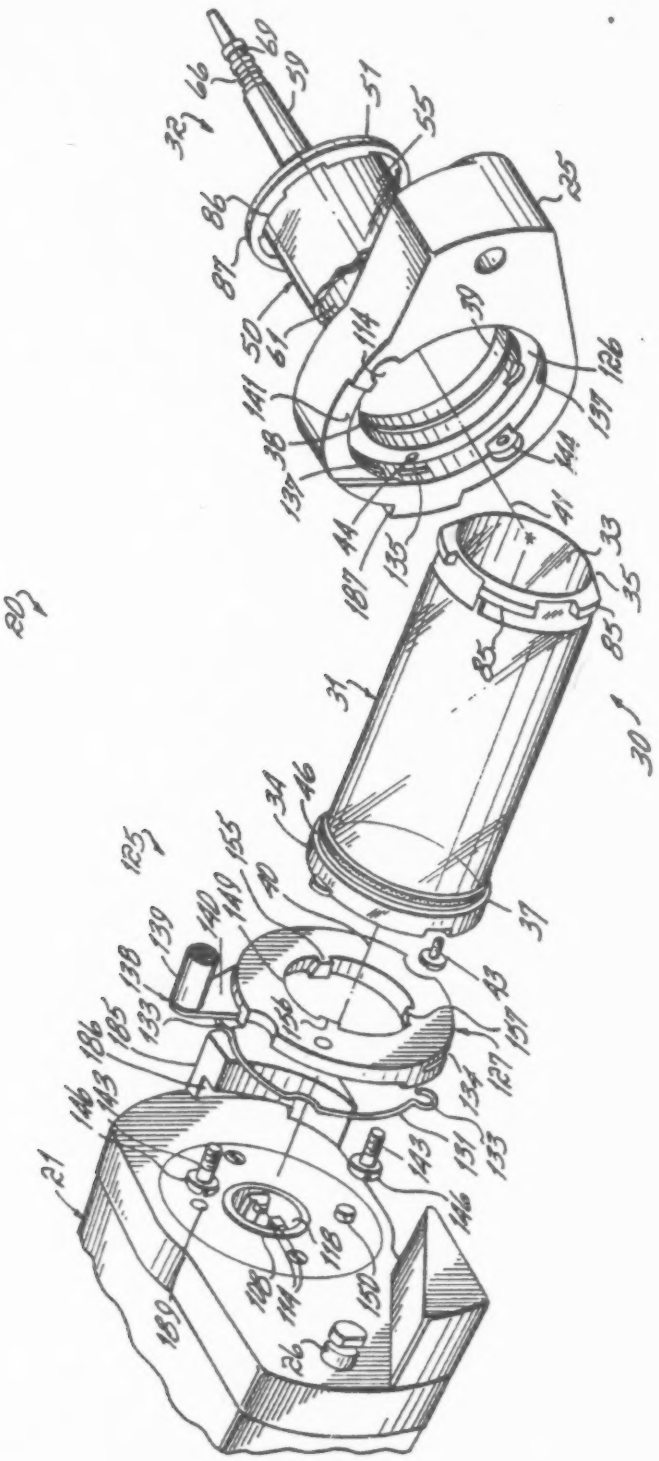

FIG. 2

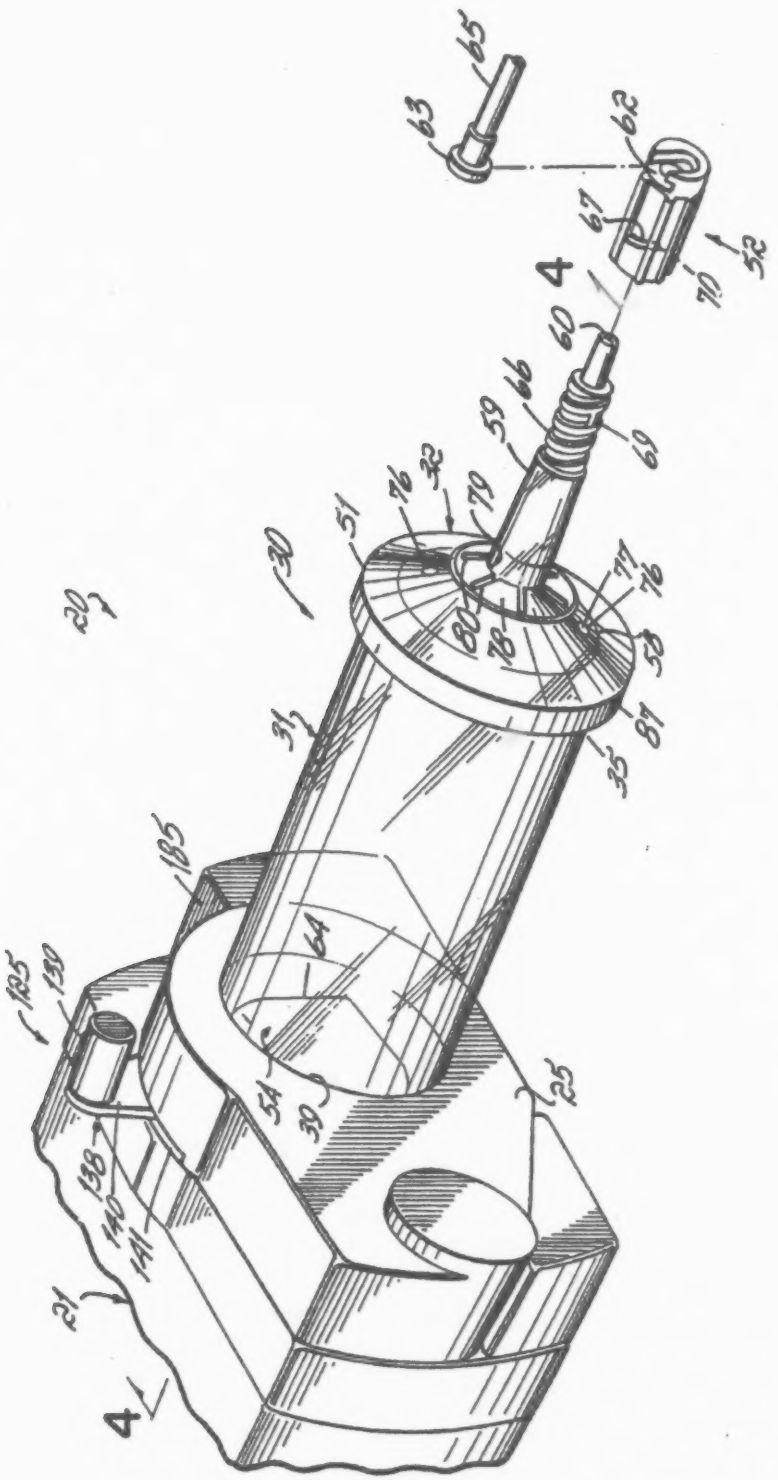
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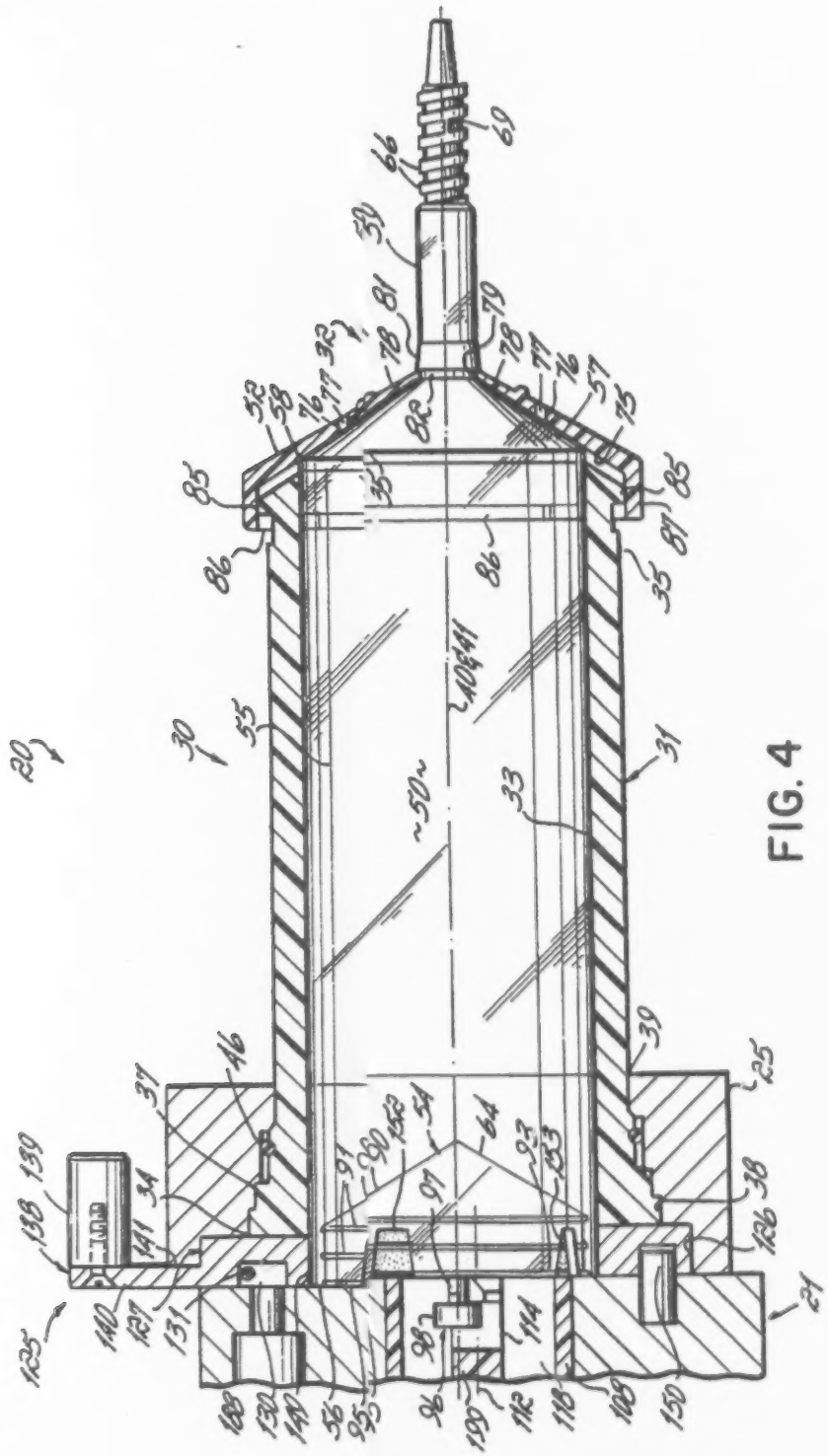
FIG. 3



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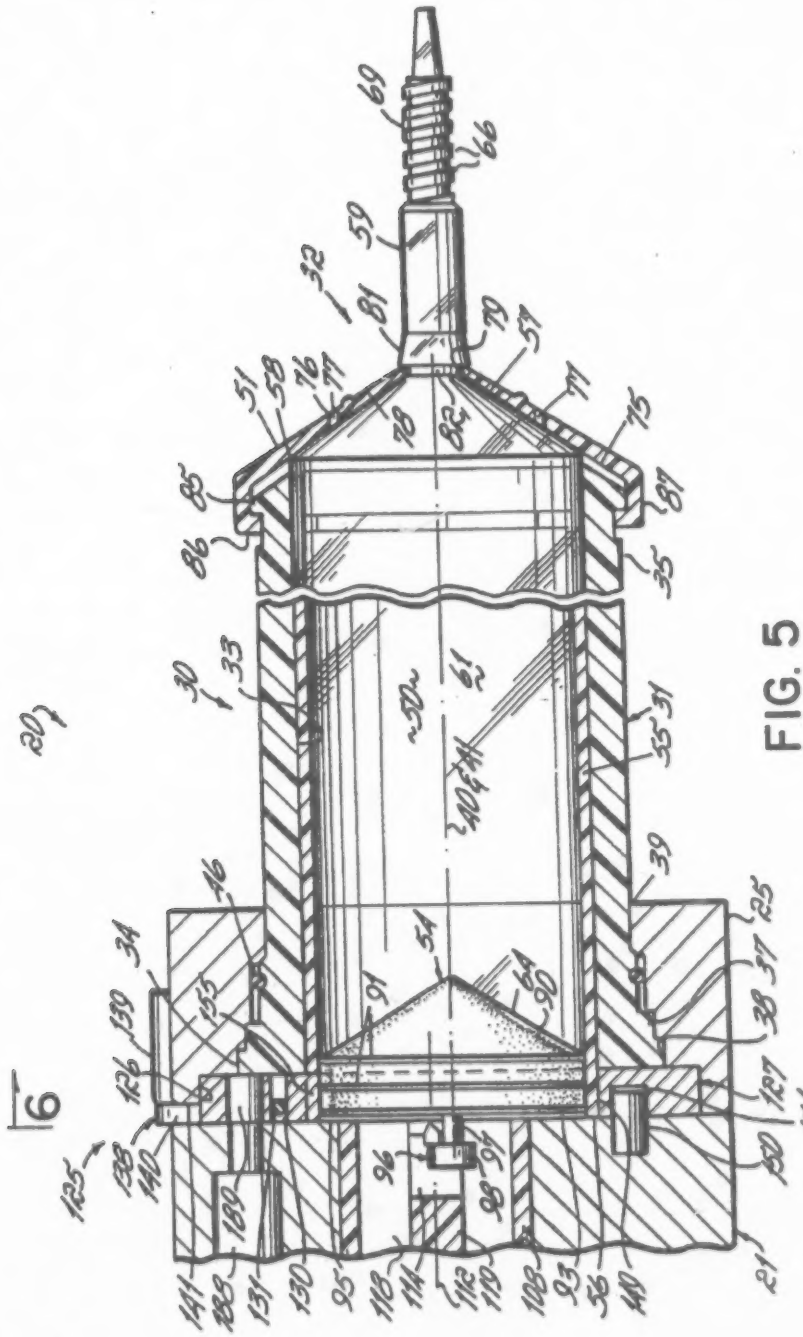
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FIG. 5

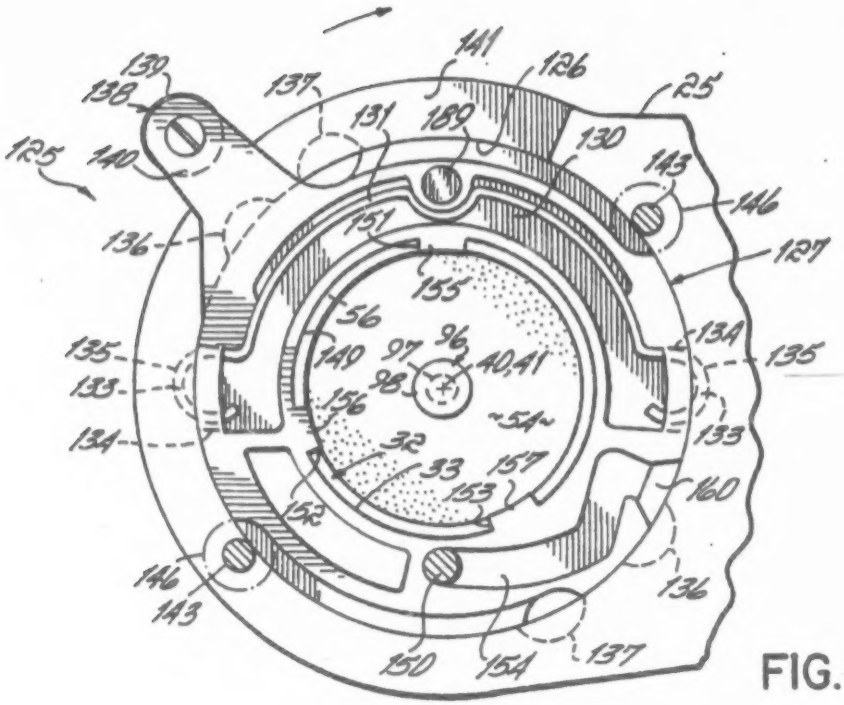


FIG. 6

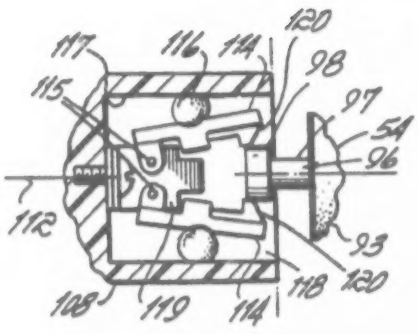


FIG. 11

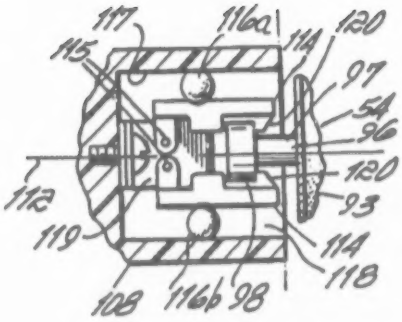
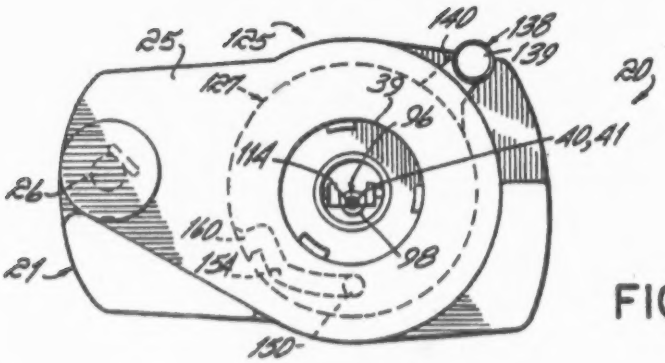


FIG. 12



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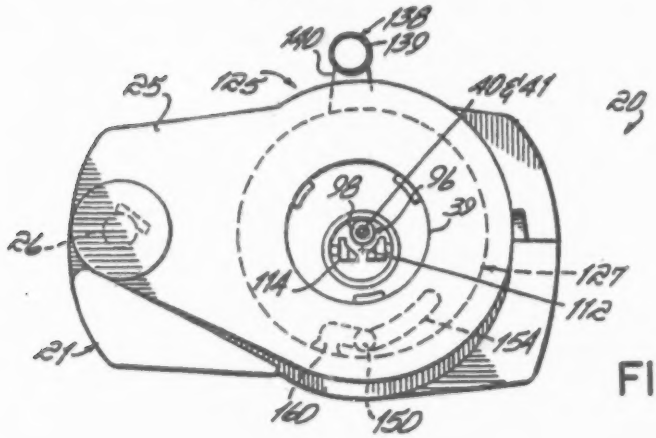

FIG. 8

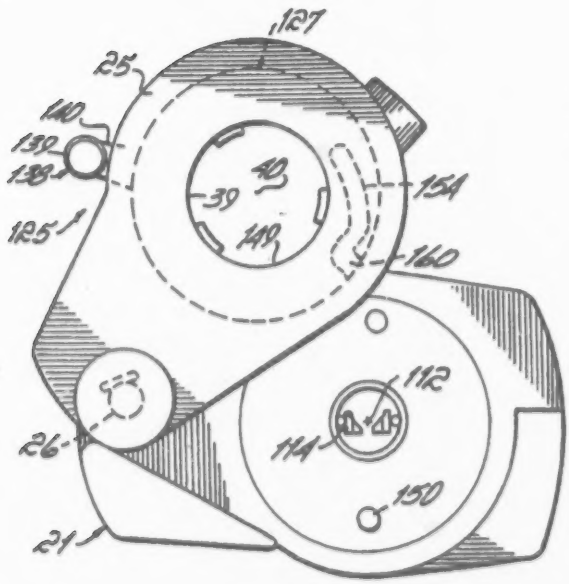

FIG. 9

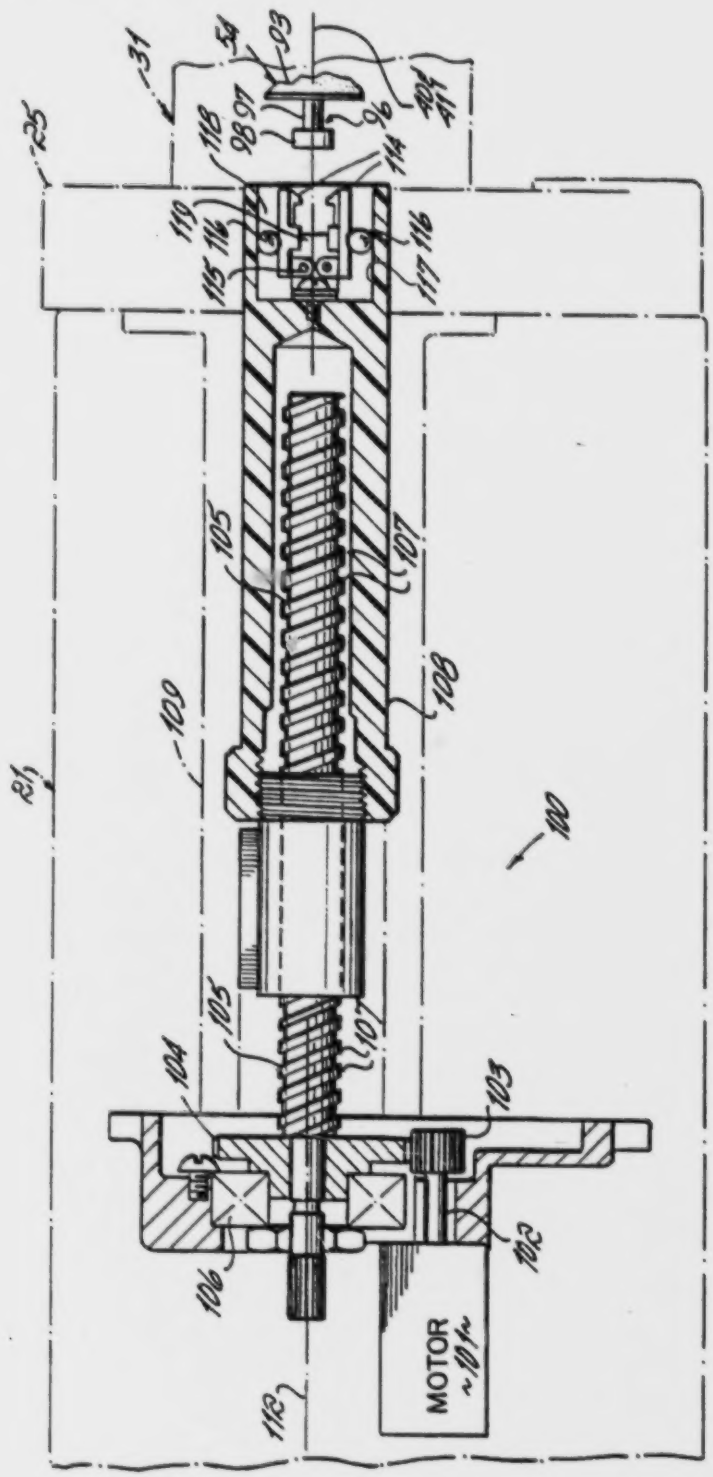

FIG. 10

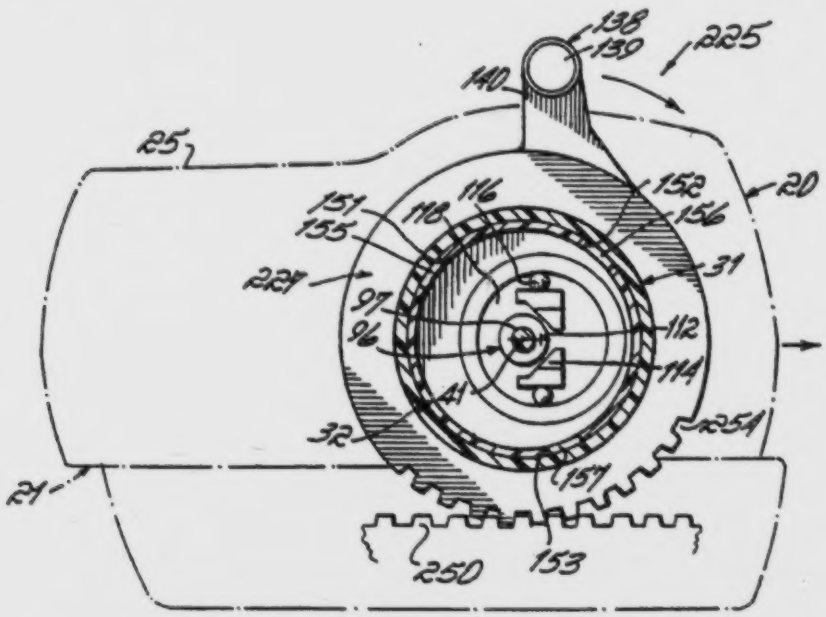
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FIG. 13

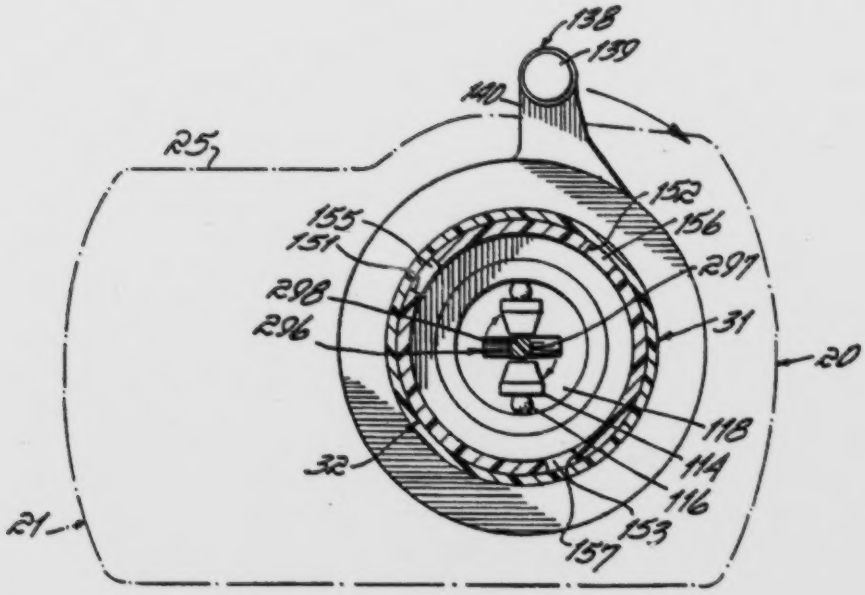
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FIG. 14

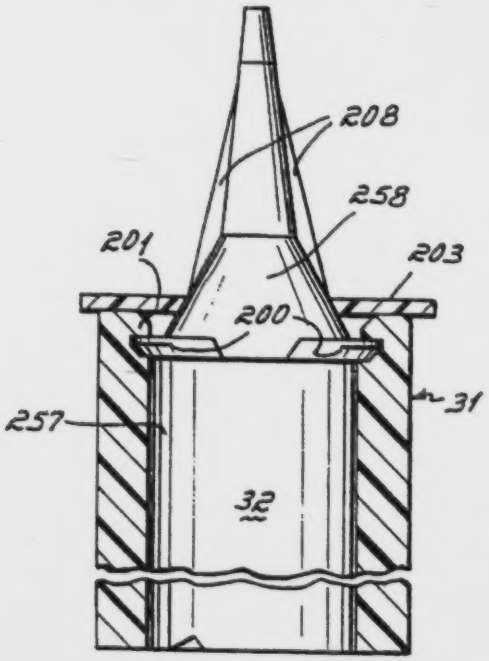

FIG. 15

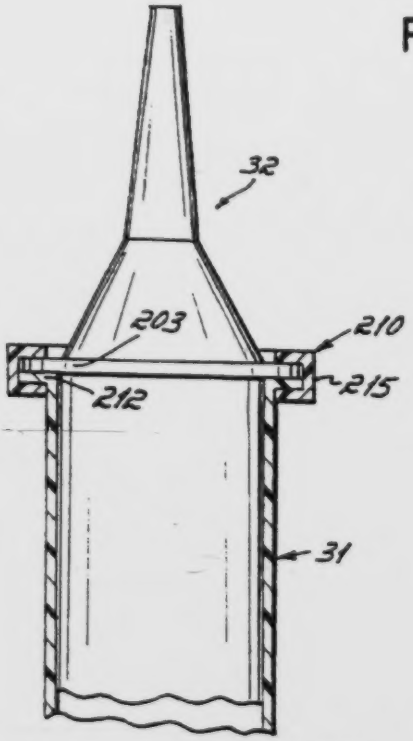

FIG. 16

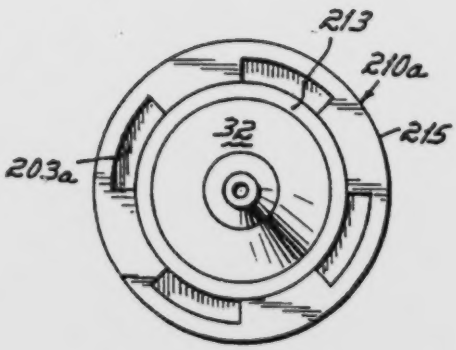

FIG. 17

METHOD OF FRONT LOADING AN INJECTOR AND INJECTING FLUID INTO ANIMALS THEREWITH

This application is a divisional of application Ser. No. 07/881,782 filed May 11, 1992, now U.S. Pat. No. 5,279,569, which is a divisional of prior application Ser. No. 07/712,110, filed Jun. 7, 1991, now U.S. Pat. No. 5,300,031.

The present invention relates to injectors and more particularly to disposable replacement syringes for animal fluid injectors.

BACKGROUND OF THE INVENTION

Injectors are devices that expel fluid, such as contrasting media, from a syringe and through a tube into an animal. The injectors are provided with an injector unit, usually adjustably fixed to a stand or support, having a drive that couples to the plunger of the syringe to drive it forward to expel fluid into the tube, or that may be driven rearward to draw fluid into the syringe to fill it. Usually the syringe is a disposable replacement type.

In the injection phase where the plunger is driven forward, pressures are developed in the syringe that range from, for example, twenty-five psi for some applications to over 1000 to 1200 psi for other applications. Syringes that will contain fluid under such pressures are expensive and therefore impractical where the syringes are to be disposable. Accordingly, many such injectors, such as angiographic injectors, for example, have been provided with pressure jackets fixed to the injector units and into which the syringes are inserted. The pressure jackets contact the outer surfaces of the syringe to restrain the walls of the syringe against the internal pressures.

To hold the syringes in the pressure jackets, the jackets of the prior art have been configured to surround the front ends of the syringes to restrain the syringe front wall against forward acting forces of the drive and the fluid pressure and to hold the syringe in the jacket. Because the front end of the pressure jacket is closed, rear loading was necessary, and accessibility thereto was provided by hinging or rotating the jacket to allow for removal and replacement of the syringe from the rear. The opening and reclosing of the injector unit to replace the syringe requires a certain amount of time, which, in the course of the procedure being performed, is not wholly desirable.

Furthermore, while for many years injector units of various types have been capable of disconnection of the plunger drive from the drive coupling on the syringe plunger at any position of the plunger within the syringe, retraction of the drive is typically required before the syringe can be removed. This is because the opening of the injector unit to remove and insert the syringe from the rear requires, for example, a translating or rotating of the jacket from the axis of the drive, which cannot be achieved if the plunger drive is extended.

For example, at the end of an injection procedure, the syringe plunger typically is forward, as is the plunger drive. Since, in the prior art injectors that load from the rear, the pressure jacket is moved through the position that the drive occupies when extended in order to remove the syringe. Hence, the syringe cannot be immediately removed without retracting the plunger drive. Further, the disposable tubing that connects to the nozzle of the syringe must be disconnected from the syringe in order to remove the syringe from the jacket. Additionally, when an empty new syringe is

inserted, the drive must be in its retracted position.

More often than not, the syringe is inserted empty and filled by retraction of the plunger with an injection tube connected to a supply of the fluid that is to be injected. In addition, before an empty new syringe can be filled, it is necessary that the plunger be fully forward in the syringe so that the syringe can be filled by rearward retraction of the plunger. As a consequence of the need with such prior art injectors to retract the drive upon loading the syringe, it is then necessary to fully advance the drive to the position in which it is in engagement with the plunger and the plunger is in its full forward position. The drive then engages a coupling on the plunger of the replacement syringe. This need to retract and advance the drive contributes to a loss of time in the syringe replacement process.

Accordingly, there has been a need to more quickly load and unload disposable replacement syringes in angiographic injectors, and for injectors and replacement syringes that can accommodate a more efficient process of syringe replacement.

SUMMARY OF THE INVENTION

It is an objective of the present invention to provide a method and apparatus by which replaceable syringes can be more efficiently loaded into and unloaded from injectors.

It is a more particular objective of the present invention to provide an injector, more particularly an angiographic injector, a replacement syringe therefor, and a method of replacing the syringe in the injector that provide for more efficient replacement of the syringes in the injector. It is an additional objective of the present invention to provide an injector wherein a used syringe can be removed and a new one inserted in the injector without retraction of the drive from the pressure jacket, in most applications. It is a further objective of the invention to allow for the removal of the used syringe from the jacket without disconnection of the injector tube from the syringe nozzle.

It is still a further objective of the present invention to provide an injector, replaceable syringe and method of syringe replacement with which the replacement of the syringe can be achieved with simple motions by the operator or with rapid operation of injector unit mechanisms.

An additional objective of the present invention is to provide an injector and replaceable syringe therefor that will facilitate control of the orientation of the syringe in the jacket, and thereby provide for positive, rapid and reliable engagement of the syringe with locking structure that holds the syringe in the jacket, engagement of the plunger drive and plunger drive coupling, or connection of the injection tube to the outlet of the syringe.

A further objective of the present invention is to provide for easy to operate mechanism and reliable locking structure for locking the syringe in place in the pressure jacket of the injection unit.

Another objective of the present invention is to provide an injector and syringe arrangement that minimizes or eliminates the probability of spillage from the syringe nozzle flowing into the injector equipment, and otherwise enhancing the ability to maintain sterility and cleanliness of the equipment.

According to the principles of the present invention, there is provided an angiographic injector having a front end loadable syringe that can be loaded into and removed from the injector pressure jacket through an opening that is

provided in the front end of the pressure jacket. To provide this front end loadable feature, the syringes of the preferred and illustrated embodiments of the present invention are provided with a front wall that is pressure restraining, that is, is of sufficient strength to support the front of the syringe against the expected pressures within the syringe, and that is securable to the front end of the pressure jacket so as to complete the pressure restraining enclosure of the syringe within the pressure jacket and hold the syringe in the jacket. In one preferred form, this front end of the injector is formed of a separate pressure restraining cap made of material that is separate from the front wall of the syringe and may be reusable. In another preferred form, the cap may be formed integrally of the front syringe wall. With the cooperating structure of the jacket and the syringe, restraining of the pressure jacket along the front and sides of the syringe is provided where the jacket allows for the replacement of the syringe from the front.

In one preferred and illustrated embodiment of the invention, the front end of the syringe locks to the front end of the pressure jacket through a cooperating engagement of mating threads on the syringe jacket. The threads include external thread sections formed at the front end of the pressure jacket and internal threads formed on an outwardly extending flange or rim of the front wall of the syringe, preferable on a pressure restraining cap. Alternatively, other securing or locking structure such as a clip or an adaptor, for example, may be employed to join the syringe to the jacket.

In the preferred embodiment of the present invention, the threads are engageable in a limited number of angular positions to thereby predetermine the angular orientation of the syringe in the pressure jacket. Additionally, other keys and keyways carried respectively by the unit and by the syringe limit the angular position in which the syringe may be inserted into the jacket to a unique predetermined angular orientation. Preferably, three keyways, such as slots or notches, unequally spaced around the back, rearward or proximate edge of the syringe body, engage similarly spaced keys or tabs on the unit at the rear end of the pressure jacket to permit insertion of the syringe into the jacket in one and only one orientation.

Further in accordance with principles of the present invention, in its preferred embodiment, a coupling on the syringe plunger is centrally located and symmetrical about the axis of the plunger. A pair of jaws on the plunger drive is moveable either by transverse straight or arcuate translatory motion or by forward longitudinal motion to form a connection between the coupling and the drive. Once coupled to the drive, the coupling remains engaged to the drive during longitudinal motion of the drive to cause the plunger to move forward or backward with the drive.

Disengagement occurs thereafter only upon transverse translational motion of the plunger with respect to the drive. In certain embodiments, this translatory transverse motion occurs by translatory movement of the jacket, and the injector unit door that carries the jacket, with respect to the plunger drive and the unit housing. In other embodiments, an asymmetrical coupling is provided that engages and disengages the plunger drive upon rotational movement of the syringe with respect to the drive.

Preferably, the motion for locking the syringe to, and unlocking the syringe from, the jacket is achieved by rotation of the syringe in the jacket, and preferably, this motion is linked to, and occurs simultaneous with, the motion that engages and disengages the plunger coupling and drive, whether that coupling is by translation or rotation. In addition, the syringe and plunger drive are so dimensioned and positioned to prevent contact between the drive and the sterile interior wall of the syringe, regardless of the position of the drive, as the syringe is being loaded.

Preferably, the syringe is formed of a cylindrical body, with the front end in the shape of a truncated cone that terminates in a forwardly extending neck with an orifice at its remote end that is connectable with an injection tube. The front end of the syringe is shaped so as to direct fluid leaking from the nozzle outwardly around the front end of the jacket. This prevents leakage, which often results upon disconnection of the injection tubing, from entering the space between the pressure jacket and the syringe body.

Replacement of the syringe begins, in the preferred embodiments of the invention, with the unlocking the syringe at its front end from the front end of the pressure jacket, preferably by rotating the syringe with respect to the jacket, and by disengaging the plunger drive from the syringe plunger, alternatively by transverse translational or rotational motion, preferably simultaneous with and linked to the motion that disengages the syringe from the jacket. The unlocking of the syringe from the jacket occurs, for example, by loosening mating threads at the front of the syringe and jacket. The twisting of the syringe in the jacket is linked to motion that either translates transversely or rotates a coupling on the syringe plunger out of engagement with the plunger drive.

Then the syringe is removed from the jacket through the open front end of the jacket. This removal may take place without retraction of the plunger drive, should the drive be advanced in the pressure jacket at the time of disengagement from the plunger coupling. The used syringe may also be removed without disconnection of the disposable injection tubing from the nozzle of the syringe.

When the used syringe is removed, a replacement syringe is inserted into the jacket through its open forward end and the front end of the new syringe is locked to the front end of the jacket, preferably by relative rotation of the syringe in the jacket to cause, for example, engagement between mating threads on the front end of the syringe and the front end of the jacket. The plunger drive, in one embodiment, is translated to bring the plunger coupling engaging jaws into alignment with the plunger coupling, preferably simultaneously with the locking of the syringe to the jacket. The jaws thereby either engage the coupling upon the translatory motion, or thereafter engage the coupling by longitudinal advancement of the drive against the coupling. In one embodiment, the jaws are positioned off center of the drive so that the drive, whether in the engaging or the disengaging positions, does not contact a syringe as the syringe is guided by the jacket during loading.

In an alternative embodiment, engagement of the plunger drive with the coupling occurs by relative rotation of the drive and the coupling, preferably by rotating the coupling relative to a stationary plunger drive, rather than by translational motion between the drive and the coupling. Only if the rest position of the plunger of the replacement syringe is behind the final position of the plunger drive at the time it was disconnected from the coupling of the plunger of the syringe being replaced need the plunger drive be retracted.

The engagement and disengagement motions between the plunger drive and plunger drive coupling, and between the syringe and the pressure jacket, are provided with manually operable mechanism that, in the preferred and illustrated embodiments, rotates the syringe in the jacket and further either rotates or translates the coupling with respect to the

plunger drive, with a simple one hand operated mechanism. The mechanism provides a convenient lever, operable through a short arc, to rotate the syringe in the jacket and to then, preferably, translate the pressure jacket that carries the syringe and is carried by the injector unit door, or to otherwise move the syringe with respect to the drive, to bring the plunger coupling of the syringe into or out of alignment with the plunger drive.

The present invention provides a disposable syringe that may be replaced in an angiographic or CT injector with great efficiency and speed. Further, replacement may occur without retraction of the plunger drive of the injector unit. Simple and rapid one hand operation of the engaging and disengaging structure is provided.

These and other objectives of the present invention will be more readily apparent from the following detailed description of the drawings in which:

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a perspective view of an angiographic CT injector embodying principles of the present invention.

FIG. **1A** is a perspective view of an another form of angiographic injector embodying principles of the present invention.

FIG. **2** is an exploded perspective view of a portion of one preferred embodiment of the injector of FIG. **1**.

FIG. **3** is a perspective view of the portion of the injector of FIG. **2**.

FIG. **4** is a cross-sectional view along lines **4—4** of FIG. **3** illustrating a replaceable syringe unlocked from the housing for insertion into or removal therefrom.

FIG. **5** is a cross-sectional view similar to FIG. **4** but illustrating the syringe locked to the structure carried by the housing.

FIG. **6** is a cross-sectional view along the line **6—6** of FIG. **5**.

FIG. **7** is an elevational diagrammatic illustration of the injector of FIG. **1** with the pressure jacket and syringe removed, and showing the syringe locking structure in the locked position such as in FIGS. **5** and **6**.

FIG. **8** is an elevational diagrammatic view similar to FIG. **7** illustrating the syringe locking structure in the unlocked position such as in FIGS. **2–4**.

FIG. **9** is an elevational diagrammatic view similar to FIG. **7** illustrating the locking mechanism in the housing door release position.

FIG. **10** is a cross-sectional view through the housing of the injector taken along lines **10—10** of FIG. **1** with the plunger drive disengaged from the syringe plunger coupling.

FIG. **11** is a view of a portion of FIG. **10** illustrating the plunger drive longitudinally moving into engagement with the plunger coupling.

FIG. **12** is a view of a portion of FIG. **10** illustrating the plunger drive in engagement with the plunger coupling.

FIG. **13** is a front view of a portion of another embodiment of the injector of FIG. **1**.

FIG. **14** is a view of an alternative embodiment of a portion of a syringe according to principles of the present invention.

FIG. **15** is a cross-sectional view similar to FIG. **5** of an alternative embodiment of the invention, illustrating alternative engaging structure between the front ends of the syringe and jacket.

FIG. **16** is a cross-sectional view similar to FIG. **5** of a further alternative embodiment of the invention, also illustrating alternative engaging structure between the front ends of the syringe and jacket.

FIG. **17** is a front end view of still a further alternative embodiment of the invention, also illustrating alternative engaging structure between the front ends of the syringe and jacket.

DETAILED DESCRIPTION OF THE DRAWINGS

Referring to FIG. **1**, an angiographic injector **10** according to another preferred embodiment of the present invention is illustrated, configured for CT applications. The injector **10** includes a ceiling mounted support **11**, adjacent a CT X-ray unit, to the lower surface of which is rigidly supported a vertically descending support column **12**.

Remote from the support **11** is an injector control module console **13** behind a wall which isolates the operator area from the X-ray equipment. The console **13** is located adjacent a control **14** of the X-ray equipment. Electrical power and control cables (not shown) communicate power and control signals through the support **11** and the column **12** and to a power lead **15**. The console **13** connects with an injector control module **16**, which includes a programmable microprocessor (not shown) to which commands and programming codes are input through a keyboard **17** on the console **13**. The console **13** is also provided with an operator display **18** to aid in interfacing the input commands and injector status with the operator.

Attached to the column **12** is an articulating adjustable arm **19**. To the remote end of the arm **19** is adjustably supported injection module unit **20**. The arm **19** is capable of setting the unit **20** at varying positions adjacent a patient bed of the CT unit.

Referring to FIG. **1A**, an angiographic injector **10***a* according to another preferred embodiment of the present invention is illustrated. The injector **10***a* includes a wheeled base **11***a* to the top of which is rigidly supported a vertically adjustable upstanding support column **12***a*. To the top of the column **12***a* is supported a control module platform **13***a*. Electrical power is communicated from a power cord (not shown) through the base **11** and the upstanding support **12***a* and through a power lead **15***a* to a control module **16***a* rigidly supported to the platform **13***a*. The control module **16***a* includes a programmable microprocessor (not shown) to which commands and programming codes are input through a keyboard **17***a* on the module **16***a*. The module **16***a* is also provided with an operator display **18***a* to aid in interfacing the input commands and injector status with the operator. Attached to the platform **13***a* is an articulating adjustable arm **19***a*. To the remote end of the arm **19***a* is adjustably supported the injection module unit **20**.

The injection module unit **20** of the embodiments of FIGS. **1** and **1A** includes a housing **21** which contains the operating drive structure of the injector **10** or **10***a*. The housing **21** has a support bracket **23** fixed thereto and adjustably pivotally supported to the remote end **24** of the articulating arm **19** or **19***a*. The housing **21** has pivotally attached to the front thereof a door **25** at the front thereof which is pivotally connected to the housing **21** at a longitudinally extending pivot or hinge pin **26** (FIG. **2**) rigidly supported on the housing **21** and extending forwardly from the front of the housing **21**.

On the top of the housing **21** is an injector position and local control panel **27** having a position indicator scale **28**

thereon, which displays the position of the injector drive to the operator. The panel **27** also includes a pair of forward and reverse drive direction control buttons **29**, which are selectively actuatable to activate a drive within the housing **21** in either the forward or reverse directions.

Extending forwardly from the front of the door **25** is an injector syringe and pressure jacket assembly **30**, the structure of which can be better understood with reference to FIGS. 2–5 below. The syringe and jacket assembly **30** includes a hard plastic pressure jacket **31**, which may be of opaque or transparent material, a removable and replaceable disposable syringe **32**, which may be of opaque, transparent or semi-transparent material, and related structure hereinafter described.

The syringe **32** is disposable, and includes walls which will withstand only moderate or low pressure. The walls are usually outwardly deformable under operating pressures, particularly pressures of 300 psi or more. Such higher pressures are necessary to overcome pressure drops through the injection tubing at higher flow rates, which are often desirable. The jacket **31** is made of a stronger transparent material that will withstand the operating pressures. When the syringe **32** is contained in the jacket **31**, it is surrounded by the jacket **31** and supported by the jacket **31** against expansion caused by the fluid pressure within as the syringe **32** expands against the jacket wall.

The pressure jacket **31** has a generally cylindrical inner bore **33** extending therethrough from a proximate end **34** adjacent the door **25** to a remote end **35** of the pressure jacket **31** toward the front of the unit **20**. The bore **33** is dimensioned so as to receive through the remote end **35** the disposable syringe **32** and to support the syringe against expansion from fluid pressure within such fluid pressure may range to more than a thousand psi. The pressure jacket **31** has an annular flange **37** extending outwardly around the proximate end **34**. The flange **37** is integrally formed with the jacket cylinder and is shaped to conform to an annular recess **38** surrounding a circular hole **39** in the door **25** to which the jacket **31** may be assembled by insertion from the rear. The hole or opening **39** in the door **25** and the cylindrical bore **33** of the jacket **31** are concentric with a longitudinal axis **40** on which also lies an axis **41** of the syringe **32** when the syringe **32** is positioned in the bore **33** of the jacket **31**. The jacket **31** is firmly and rigidly attached to the door **25** with a pair of screws **43**, only one of which is shown, which are threaded into a pair of holes **44** in the back of the door **25** (FIG. **2**). An O-ring seal **46** surrounds the flange **37** of the jacket **31** in the recess **38** of the door **25**.

The syringe **32** includes a syringe case **50** formed of a single piece of molded plastic material, a pressure cap **51**, a tubing collar **52** (FIG. 3) and a plunger **54** (FIGS. 3–5). The syringe case **50** includes a cylindrical syringe body **55** having an open proximate end **56** and a remote end **58** to which is integrally formed a conical front wall **57**. The front wall **57** is truncated at its forward end, to which is integrally formed an elongated neck **59** extending from the wall **57** at the center thereof. The neck **59** of the syringe case **50** has an orifice **60** (FIG. 3) in its remote end which communicates with an internal syringe cavity **61** formed within the neck **59**, the conical front wall **57** and the cylindrical body **55** of the case **50** of the syringe **32**. The rear end of the cavity **61** is further defined by a forward facing conical surface **64** of the plunger **54**. The conical surface **64** is of a slope which conforms to the slope of the interior of the conical front wall **57**. The plunger **54** is slidable within the body **55** of the syringe case **50** such that the cavity **61** is of variable volume.

Near the front end of the neck **59** of the syringe case **50**, just behind the orifice **60**, is an external thread **66** configured to mate with threads **67** on the interior of collar **52** (FIG. 3). The thread **66** in the neck **59** has an stop **69** at near forward end thereof to engage an abrupt step **70** on the thread **67** of the collar **52** so that, when the syringe **32** is properly oriented in the jacket **31**, the collar **52**, when loosened to its maximum extent, will assume a predetermined orientation so as to present, in an upwardly facing orientation, a tube end receiving slot **62** formed in the remote end of the collar **52**. This slot **62** is of T-shaped cross-section so as to receive the enlarged flange end **63** of a tube **65** through which fluid from the syringe cavity **61** is injected into a patient.

The cap **51** is generally conical in shape and has an inner rearward surface **75**, which conforms to the front surface of the conical wall **57** of the case **50** of the syringe **32**. In certain embodiments, the rearward conical surface **75** of the cap **51** may be bonded to the front surface of the conical wall **57** of the case **50** of the syringe **32**, or it may be formed integrally therewith, molded from the same plastic material as the case **50** of the syringe **32**. In the preferred and illustrated embodiment, the cap **51** is separate from the syringe body portion **55** and has a pair of holes or detents **76** into which fit a pair of projections **77** extending forwardly from and formed integrally on the outer surface of the conical wall **57** of the case **50** of the syringe **32**. The cooperation of the pins or projections **77** with the holes or detents **76** prevent the cap from rotating with respect to the syringe case **50** when the cap **51** is mounted on the syringe **32**.

To hold the cap **51** against the conical wall **57** of the case **50** of the syringe **32**, six resilient tabs **78** are formed about a central inner hole **79** of the cap **51**. The tabs **78** are separated by six equally spaced radial slots **80** (FIG. 3). The hole **79** in the cap **51** is equal to or only slightly greater in size than the circular forward end of the conical wall **57** of the case **50** of the syringe **32**. The neck **59** of the syringe **32** has an enlarged straight section **81** slightly greater in diameter than the hole **79** in the cap **51** and also greater in diameter than the forward end of the conical wall **57** of the case **50**, thereby forming a groove **82** at the juncture of the straight neck portion **81** with the conical wall **57** so that the tips of the tabs **78**, which are sufficiently resilient to slide over the enlarged neck portion **81** as the cap **51** is inserted on the case **50** of the syringe **32** with the hole **79** surrounding the neck **59** to snap fit into the groove **82**.

The syringe **32** includes structure that is configured to lock the syringe **32** to the front end of the jacket **31** by cooperating with mating structure on the jacket **31**. The jacket **31** has, spaced around the circumference thereof near the remote or front end **35** of the jacket **31**, four equally spaced outwardly projecting thread sections **85**. These thread sections **85** are slightly less than 45° in extension around the circumference of the jacket **31** and are spaced apart with gaps of slightly greater than 45°. The cap **51** has a cylindrical rim **87** in which are formed four similarly sized and spaced mating thread sections **86**. The thread sections **86** project inwardly toward the jacket **31** when the syringe **32** is positioned in the jacket **31**. As such, when the syringe **32**, with the cap **51** assembled to it is inserted into the jacket **31**, the threads **86** of the cap **51** pass through the spaces between the threads **85** on the jacket **31** to a point behind the threads **85**. When so inserted, the syringe assembly **32** with the cap **51** may be twisted clockwise 45° to tighten and thereby secure the cap **51** to the jacket **31** by engagement between the threads **85** and **86** as shown in FIG. 5, to thereby lock the syringe in the bore **33**.

The piston **54** of the syringe **32** is molded of an elastomeric material. Preferably, the piston **54** includes two por-

tions molded of different materials and bonded together. These portions include a forward more flexible portion **90** in which is formed the forward conical surface **34**. This forward portion **90** has a pair of outwardly extending rings **91** formed in the periphery thereof to make sealing engagement with the inside of the wall of the cylindrical body **55** of the syringe case **50**. The rearward portion of the piston **54** is a flat circular surface to which is bonded the flat circular forward surface of a more rigid rear portion **93** of the piston **54**. The rear rigid portion **93** of the piston **54** is molded of a harder stronger plastic material and has a rearward facing circular surface **95** having a rearward extending coupling **96** integrally formed thereon at its center. The coupling **96** includes a rearwardly extending cylindrical shaft **97** on the axis **41** of the syringe **32** and a larger symmetrical cylindrical button **98** integrally formed at the rear end of the cylindrical shaft **97**.

Referring to FIG. **10**, a piston drive assembly **100** is illustrated contained within the housing **21**. The drive assembly **100** includes an electric motor **101** mounted within the fixed housing **21** and having a rotary output shaft **102** with a drive gear **103** fixed to the remote end thereof. The drive gear **103** is positioned for driving engagement with a driven gear **104** fixed near the rear end of a drive screw or shaft **105** supported at its rear end in a bearing **106** fixed in the housing **21**. The screw or shaft **105** has a continuous external helical thread **107** thereon which mates with interior threads of a carriage **108**. The carriage **108** is slidably supported in a bushing **109** fixed in the housing **21**. The shaft **105** rotates within the housing **21** about a longitudinal axis **112**.

At the forward end of the carriage **108** is supported a pair of hooked jaws **114** which are pivotally mounted at their rearward ends by a pair of pivot pins **115** to the carriage **108**. The jaws **114** are biased toward the axis **112** by a pair of balls **116***a* and **116***b* of resilient material positioned between the outside of the jaws **114** and an inner cylindrical wall **117** of a recess **118** formed in the forward end of the carriage **108**. The balls **116***a*, **116***b* are partially captured in depressions in the outer surfaces of the jaws **114**. The balls **116***a*, **116***b* bias the jaws toward their innermost position toward the axis **112**. The innermost position of the jaws is determined by a spacing block **119** on the axis **112** of the carriage **108** at the center of the cavity **118**.

When a syringe **32** is locked in the jacket **31** with its axis **41** and the axis **40** of the jacket **31** may be in alignment with the axis **112** of the shaft **105**, the plunger **54** may be located in the cylindrical body **55** of the syringe case **50** in a position forward of the remote end **56**. Preferably, however, the jaws **114** are displaced to the side of axis **112** of the shaft **105** so that as the jaws **114** and coupling tip **98** are in their disengagement position, maximum clearance is provided so that the syringe **32** may be inserted into the jacket **31** without the sterile internal walls of the syringe **31** touching the components of the drive, as illustrated in the figures.

In the engaging position, the jaws **114** are nonetheless in alignment with the coupling **98** on the axes **40** and **41** of the jacket **32** and syringe **32**. In such a situation, the jaws **114** may be in a retracted position at the center of the opening **39** of the door **25** adjacent to the proximate end **34** of the jacket **31**, and out of engagement with the coupling **96** on the plunger **54**. From this position, operation of the motor **101** rotates the shaft **105** and drives the carriage **108** forwardly to move the jaws **114** toward and into engagement with the coupling **96** on the plunger **54**. This engagement takes place as shown in FIG. **11** where a pair of tapered cam surfaces **120** at the forward interface of the tips of the jaws **114** engage the enlarged portion or button **98** of the coupling **96** to expand the jaws, as shown in FIG. **11**, to snap around the button **98** of the coupling **96** to form a driving engagement between the drive assembly **100** and the coupling **96** of the plunger **54** as shown in FIG. **12**. Once so engaged, any forward or reverse movement of the carriage **108** under the power of the motor **101** will cause the plunger **54** to be driven either forwardly or backwardly in the syringe body **55**.

Disengagement of the jaws **114** from the coupling **96** can thereafter be achieved by translational movement between the coupling **96** and the jaws **114** between a disengaged position as shown in FIG. **4** and an engaged position as shown in FIG. **5**. When the plunger coupling **96** and the jaws **114** are disengaged, the syringe **32** can be replaced without the need to retract the carriage **108** of the drive **100**. This allows for rapid replacement of the syringe **32**. Preferably, the jaws **114** are either fully retracted toward the housing **21** where engagement by translation of the coupling **96** will occur, or the jaws **114** are sufficiently within the jacket prior to replacement of the syringe so that the coupling **96** of the replacement syringe **32** will not contact the jaws **114** except as the drive **100** is advanced.

If sterility is not a problem, the most time saving approach would be to insert the syringe **32** into the jacket **31** with its plunger all the way forward and the drive fully advanced so that, when the syringe is translated toward the jaws **114**, engagement will immediately occur and the plunger can be immediately retracted to fill the syringe.

When a syringe **32** is inserted into the jacket **31** when the plunger **54** is at its rearmost position toward the proximate end **56** of the syringe body **55**, the coupling **96** is in a position adjacent the proximate end **56** of the syringe body **55** and projecting rearwardly therebeyond. When in such a position, engagement between the jaws **114** and the coupling **96** is brought about by translational movement between the position shown in FIG. **4** and that shown in FIG. **5**. In the unlocked or disengaged position shown in FIG. **4**, the axes **40** and **41** of the jacket **31** and the syringe **32**, respectively, as well as the center of the opening **39** of the door **25**, lie spaced from and parallel to the axis **112** of the shaft **105** as shown in FIG. **4**. In the locked or engaged position, the axis **112** of the shaft **105** is slightly eccentric relative to the axes **40** and **41** of the jacket **31** and syringe **32**, respectively, as shown in FIG. **5**. This translational movement, the engagement and disengagement between the coupling **96** and the jaws **114** and the 45° rotational movement which secures the cap **51** to the pressure jacket **31** by engagement of the threads **85** and **86** are brought about by operation of a translating and locking mechanism **125**, which is best understood by reference to FIGS. **2–9**.

The translating and locking mechanism **125** includes a cam and locking ring **127** which is rotatably retained in a circular recess **126** in the back of the door **25**. The ring **127** has a generally semi-circular groove **130** in the back surface thereof for receiving a spring wire retaining clip **131** having a pair of looped ends **133** which extend through a pair of slots **134** in the rim of the ring **127** and into a selected one of three pair of diametrically opposed notches **135**, **136** and **137** in the inner wall of the rim of the recess **126** in the door **25**. The three pair of notches **135**, **136** and **137** represent three positions of the translating and locking mechanism **125** which are the locked, unlocked and release positions, respectively. The locked position of the mechanism **125** in which the loops **133** of the ring **131** are in the notches **135**, is that illustrated in FIGS. **5–7** and **10**. The unlocked position, in which the loops **133** of the ring **131** are in the

notches 136, is that illustrated in FIGS. 2–4 and 8. The release position, in which the loops 135 of the clip 133 are in notches 137, is that illustrated in FIG. 9. The ring 127 is moved among these three positions by a manually accessible handle 138 in the form of a cylindrical knob 139 rotatably attached to a lever arm 140 formed integrally and extending radially from the ring 127 through a slot 141 in the door 25 (FIG. 1). The ring 127 is retained in the recess 126 by a pair of screws 143 which thread into countersunk holes 144 at the periphery of the recess 126 in the back of the door 25. These screws 143 have enlarged heads 146, which, when seated in the holes 144, overlie the edge of the ring 127, thereby securing it for rotatable movement within the recess 126.

As shown in FIGS. 2 and 6, the ring 127 has an inner periphery 149 which is larger than the circumference of the body 55 of the syringe case 50. Accordingly, when the syringe 32 is inserted in the jacket 31, the proximate end 56 of the syringe case 50 extends through and is surrounded by the inner periphery 149 of the ring 127. Asymmetric keyway structure, preferably in the form of three slots or notches 151, 152 and 153 (FIG. 6) are provided in the edge of the proximate end 56 of the body 55 of the syringe case 50. The spacings between adjacent pairs of the notches 151–153 differ from each other. Formed integrally of the ring 127 and projecting inwardly from the inner periphery 149 thereof are three tabs or keys 155, 156 and 157. These tabs 155–157 are spaced so as to fit into the respective notches 151–153 in the proximate end 56 of the body 55 of the syringe case 50 so as to rotate the syringe 32 as the mechanism 125 is rotated through actuation of the handle 138. Because the notches 151–153 and the tabs 155–157 are unequally spaced, they can only engage each other when the syringe 32 is inserted into the jacket 31 in one and only one orientation. That orientation is one which will cause the slot 62 of the collar 52 (FIG. 3) to align 45° counterclockwise of the vertical when the mechanism 125 is in its unlocked position, which is a position in which it will be when the syringe is first inserted into the jacket 31, and to be in an upwardly facing orientation, when fully loosened, when the mechanism 125 is moved to its locked position. Accordingly, the notches 135 and 136 in the recess 126, which receive the loops 133 of the spring clip 131 when respectively in the locked and unlocked positions, are 45° apart.

The rotation of the mechanism 125 from the unlocked position to the locked position rotates the syringe 32 in the jacket 31 and rotates the cap such that its threads move from an unlocked position as shown in FIG. 4 to the locked position of FIG. 5, to secure the cap to the jacket 31 by the engagement and tightening of the threads 85 and 86.

The translational movement of the axes 40 and 41 with respect to the axis 112 is achieved by a fixed cylindrical cam follower or pin 150 which projects outwardly from the fixed housing portion 22 behind the ring 127 and into a cam slot 154 formed therein. The slot 154 is shaped so that the axes 40 and 41 which remain fixed with respect to the ring 127, along with the door 25, the jacket 31, the syringe 32 and all of the structure mutually carried thereby, are moved in relation to the axis 112 of the shaft 105 and the other structure mutually carried by the housing 22, as the mechanism 125 is rotated. These axes move toward and away from each other in accordance with the shape of the slot 154 determined by the radial distance from the point along the slot 154 where it engages the pin 150 to the axes 40 and 41.

The cam slot 154 in the ring 127 is shaped such that, when the mechanism 125 is in the locked position as shown, for example, in FIGS. 6 and 7, the distance between the pin 150 and the axes 40 and 41 is at a minimum and the axis 112 coincides with the axes 40 and 41. This is illustrated in FIGS. 5 and 7 wherein the coupling 96 is shown positioned between the jaws 114 and in mutual engagement therewith. When the mechanism 125 is in the unlocked position, with the loops 133 of clip 131 in the notches 135 (FIG. 6) of the recess 126, the pin 150 lies in the slot 154 in the position shown in FIG. 8, which is farther displaced from the axes 40 and 41 than in the position of FIGS. 6 and 7, so that the coupling 96 is translated to a position outside of the center line of the jaws 114, as shown in FIG. 8 and further illustrated in FIG. 4.

In the release position, as shown in FIG. 9, the pin 150 is positioned at the open end 160 of the cam surface of the slot 154 so that the door 25 can be rotated upwardly about the hinge pin 26, as shown in FIG. 9, to open the space behind the door 25 for access thereto. This position may be used for cleaning the area behind the door 25 which is sometimes necessary because of possible leakage of fluid from the cavity 61 into the space behind the plunger 54. This can possibly occur because the fluid within the cavity 61, when being injected by forward advancement of the plunger 54, may be of relatively high pressure in the range, usually over 200 psi. For applications such as the injection of contrasting fluid for CT scanning, pressure may typically be in the range of from 25 to 300 psi., while in some angiographic injection applications the pressure may range to 1200 psi or higher.

In addition, leakage rearwardly along the exterior of the neck 59 of the syringe 32 can cause fluid to flow between the body portion 55 of the syringe 32 and the jacket 31. For this reason, the cap 51 is caused to fit snugly against the forward surface of the conical portion 57 of the syringe 32 at least sufficiently to restrict the flow of this leaking fluid onto the neck 59. This is assisted by the configuration of the cap 51 at the rim 87 thereof so as to divert away from the space between the syringe 32 and jacket 31 fluid which might leak from the nozzle.

The front of the housing 21 has formed thereon a door stop 185 having a slot 186 formed therein for receiving a lug 187 of the door 25, to restrain the door 25 against forward force exerted by the drive 100. Behind the front of the housing 21 adjacent the stop 185 is a magnetic sensor 188, which is responsive to the presence of a magnet 189 in the lever arm 139 of the handle 138. The sensor 188 generates a signal to the control module 16 to activate the drive 100 only when the mechanism 125 is in its locked position.

Referring to FIG. 13, there is illustrated a locking mechanism 225 that is an alternative to the locking mechanism 125 described above. In the locking mechanism 225, a stationary geared rack 250 is provided fixed to the housing 21. A mating gear segment 254 is formed on the outer rim of the alternative locking ring 227 of this embodiment. The gear segment 254 and rack 250 replace and function in the same way as the slot 154 and pin 150 of the embodiment described above. As the mechanism 225 is rotated by the handle 138, the door 25 that carries the jacket 31 and the syringe 32 is translated to bring the coupling 96 into or out of engagement with the jaws 114 of the drive 100. Simultaneous with this translatory motion, the syringe 32 is rotated in the jacket 31 to lock or unlock the syringe 32 to the jacket 31 by engagement or disengagement of the threads 86 on the syringe 32 with the threads 85 on the jacket 32.

FIG. 14 illustrates an alternative to the embodiment of the coupling 96 described above. In the embodiment of FIG. 14, there is provided a coupling 296 that is T-shaped, having a rectangular endpiece 298 at the rearward end of a cylindrical or square shaft 297 on the rearwardly facing circular surface

95 of the plunger 54. Such a coupling 296 engages the jaws 114 by rotation of the locking mechanism 125 or 225, preferably through an angle of 90°. When the orientation of the endpiece 298 is parallel to the plane of the jaws 114, the drive 100 is locked to the plunger 54 so that axial movement of the drive 100 moves the plunger axially, in the forward direction to expel fluid form the syringe cavity 61, or in a rearward direction to fill the cavity 61 with fluid. When the endpiece 298 is perpendicular to the plane of the jaws 114, the coupling 296 will move into or out of engagement with the jaws 114 upon relative axial movement between the plunger 54 and the drive 100. Thus, with this embodiment, rotational motion, rather than translational motion, causes engagement and disengagement of the coupling 296 by the jaws 114. With this embodiment, orientation of the syringe 32, when loaded into the jacket 31, is preferably maintained through the cooperation of the notches 151–153 and the tabs 154–156 (FIG. 4), so that the coupling 296 will enter the jaws 114, when the syringe 32 is inserted into the jacket 31, with the endpiece 298 perpendicular to the pair of jaws 114.

The locking structure between the syringe 32 and the pressure jacket 31 should provide for retention of the syringe 32 in the jacket 31 against the force of the fluid pressure in the cavity 61 or axial force otherwise exerted on the plunger 54 by the drive 100. This locking of the syringe 32 to the jacket 31 is preferably achieved, as shown in FIG. 5, by structure at or near the forward wall 57 of the syringe case 50. In accordance with the embodiment of FIG. 15, such structure may include external threads 200 on the forward end of the syringe body 257, which mate with internal threads 201 at the remote end of the jacket 31. With such an embodiment, the syringe 32 is preferably provided with an annular flange 203 around the body 257 at the juncture of the body 257 with the syringe front wall 258. The flange 203 inhibits the flow of leaked fluid into the space between the syringe body 257 and the jacket 31. With such an embodiment, the wall 258 is either thickened, provided with reinforcing such as the ribs 208, or provided with other structure to resist deformation of the wall 258 under the pressure of the fluid within the cavity 61.

Alternatively, a reusable split clip 210 may be employed to secure a continuous flange 203 of such a syringe to a continuous flange 212 at the end of the pressure jacket in the embodiment of FIGS. 16. As a further alternative as shown in FIG. 17, a ring clip 210a having an outer rim 215 and rotatably mounted to the syringe 31, encircles and engages outwardly projecting threads of a disk flange 213 formed at the front end of the jacket 31, as the syringe 32 is twisted onto the jacket 31, to engage the jacket in a manner similar to the threads 85 and 86 in the embodiment of FIGS. 2–12 above.

The invention has been described in the context of its preferred embodiments. It will be appreciated by those skilled in the art that variations and alternatives to the embodiments described may be employed without departing from the principles of the present invention. Accordingly, this patent is not intended to be limited except by the scope of the following claims:

We claim:

1. A method of loading an empty syringe into a power injector for injecting fluid into an animal and for filling the syringe with the fluid to be so injected, wherein the injector has a syringe receiving opening therein and a power driven ram extendable through the opening, the method comprising the steps of:

providing adjacent the opening an empty syringe having a tubular body having a hollow interior therein, an open rearward end communicating with the hollow interior, and a closed forward end having a discharge orifice therethrough, the syringe having a plunger moveable in the hollow interior between the rearward end and forward end, the plunger being in an initial position proximate the forward end;

translating the rearward end of the syringe longitudinally rearwardly from adjacent the opening toward and into the opening to load the injector with the syringe;

locking the syringe when in the opening to the injector;

providing the ram in a forward position extending through the opening and the rearward end of the body of the syringe and into the hollow interior of the syringe;

coupling the ram in the interior of the syringe to the plunger;

connecting a supply of fluid to the discharge orifice;

energizing a ram drive to translate the coupled ram rearwardly from the forward position to thereby move the plunger rearwardly in the body to draw fluid into the interior of the syringe through the orifice from the connected supply.

2. The method of claim 1 further comprising the steps of:

after drawing fluid into the interior of the syringe body, disconnecting the supply from the orifice; then,

connecting a tube between the orifice and the animal; then,

energizing the ram drive to translate the ram forwardly in a programmed motion to thereby translate the plunger forwardly to inject a programmed flow of fluid from the hollow interior, through the orifice and into the cardiovascular system of the animal.

3. The method of claim 1 wherein:

the ram is provided in the forward position before the rearward end of the syringe is translated longitudinally rearwardly whereby the ram extends through the opening into the hollow interior of the syringe.

4. The method of claim 1 wherein:

the syringe locking step and the ram coupling step are performed simultaneously.

5. The method of claim 1 wherein:

the syringe locking step and the ram coupling step are both carried out by rotating the syringe.

6. A method of loading a syringe into an injector, where the syringe has a hollow tubular body enclosing an interior therein, an open rearward end communicating with the hollow interior, and a closed forward end having a discharge orifice therethrough, the syringe having a plunger slidable within the body, and the injector has a power driven ram for moving the plunger of the syringe, when loaded on the injector, longitudinally in the body to inject fluid into an animal the method comprising the steps of:

positioning the syringe adjacent the injector and, with the ram extended toward the syringe, moving the body of the syringe rearwardly toward the injector so that the ram enters through the open rearward end of the syringe and into the interior;

while rearwardly moving the syringe, guiding, with structure supported on the injector, the body of the syringe so as to maintain the body out of contact with the ram;

connecting the body of the syringe to the injector;

coupling the plunger to the ram; and

applying power to the ram and therewith retracting the ram toward the injector to thereby rearwardly slide the plunger in the body and thereby fill the syringe with

fluid drawn through the orifice.

7. The method of claim 6 further comprising the steps of:

connecting the orifice through a tube to the animal;

applying additional power to the ram to translate the ram forward at a programmed speed and thereby translate the plunger forwardly at the programmed speed to inject the fluid from the filled syringe, through the orifice and through the tube at a programmed rate into the body of the animal.

8. The method of claim 6 wherein:

the syringe body connecting step and the plunger coupling step are performed simultaneously.

9. The method of claim 6 wherein:

the syringe body connecting step and the ram coupling step are both carried out by rotating the syringe body relative to the injector.

10. A method of loading a tubular replacement syringe into a high pressure power injector for injecting fluid into an animal, the method comprising the steps of:

providing a power injector having:

a syringe receiving opening with a generally circular periphery therein adapted to receive a rearward end of a syringe having a generally circular rim,

a ram and a motor linked to the ram and operable to reciprocate the ram along a segment of a line projecting through the opening; and providing a hollow tubular syringe that includes:

a cylindrical body having an axis, a generally circular rim, a rearward end and a closed forward end with a fluid discharge orifice therein, and

a plunger axially slidable in the body, the syringe body being structurally capable of withstanding, at least from the rim to the orifice, fluid at an operating pressure of at least 100 psi within the interior thereof;

then:

inserting into the opening, by generally rearward axial movement of the syringe, the rearward end of the body;

rotating the syringe in the opening a fraction of a turn to thereby lock the body around the rim to the injector around the periphery of the opening; and

engaging the plunger with the ram;

then:

energizing the motor and thereby driving the ram forward along the line and parallel to the axis to move the plunger axially forward at a programmed speed to inject the fluid at the operating pressure from within the syringe and through the orifice at a programmed rate into the animal.

11. The method of claim 10 further comprising the steps of:

providing a cooperating coupling elements on the ram and the plunger for releasably coupling the ram and the plunger;

providing linkage interrelating rotation of the syringe relative to the injector and movement of the coupling elements relative to each other;

imparting to the syringe a releasing motion to rotate the syringe relative to the opening and thereby unlock the syringe from the injector and to uncouple the plunger from the ram; and

removing the syringe from the injector by generally forward axial movement of the syringe from the opening.

12. The method of claim 11 wherein:

the motion imparting step includes the step of translating the plunger transversely relative to the ram to uncouple the plunger from the ram in a motion linked to the rotation of the syringe relative to the opening.

13. The method of claim 10 wherein:

the step of locking of the syringe body to the injector includes the step of threading the rim around the opening.

14. The method of claim 10 wherein:

the injector includes a hollow pressure jacket projecting therefrom having an open front end, the opening being located at the front end of the pressure jacket, the jacket having an internal cross-section dimensioned to surround and provide pressure restraining exterior support to the body of a syringe, inserted in the jacket through the opening, between at least the rearward end of the body to the rim;

the peripheral rim of the syringe is located at the forward end thereof;

the syringe inserting step includes the step of translating the syringe rearwardly and inserting thereby the body of the syringe, from the rearward end to the rim, into the jacket; and

the rotating step includes the step of locking the forward end of the syringe to the front end of the jacket.

15. The method of claim 14 wherein:

the plunger engaging step occurs upon the performance of the syringe rotating step.

16. The method of claim 10 wherein:

the syringe rotating step and the plunger engaging step are performed simultaneously.

17. The method of claim 10 wherein:

the engaging of the plunger with the ram occurs upon the performance of the syringe rotating step.

18. The method of claim 10 further comprising the step of:

after engaging the plunger with the ram and before the step of energizing the motor and thereby driving the ram forward, retracting the ram and thereby rearwardly moving the plunger and thereby drawing fluid into the syringe through the orifice.

19. A method of removing a disposable syringe from a power injector after injecting fluid into an animal therewith, the injector having a powered ram extendable from the front end thereof, the method comprising the step of:

providing the injector having an opening at the front end of the injector dimensioned to receive the back end of a disposable syringe therein such that the ram is extendable into an open rearward end of a syringe inserted in the opening;

providing the disposable syringe having an open rearward end inserted in the opening and locked to the injector, the syringe further having a hollow body, a plunger slidably mounted in the body and coupled to the ram of the injector, and a closed forward end having an orifice therein;

providing fluid in the hollow interior of the syringe;

providing a tube connected between the and the animal;

then:

driving the ram forward to move the plunger axially forward at a programmed speed to inject the fluid at a programmed rate from the interior of the syringe through the orifice and the tube and into the animal;

then:

unlocking the syringe from the injector and removing the syringe from the opening by forward axial movement thereof with the tube connected to the orifice of the syringe.

20. A method of replacing a tubular replacement syringe in a high pressure power injector for injecting fluid into an animal, the method comprising the steps of:

providing the power injector with a generally circular opening in the front thereof adapted to receive the rearward end of a syringe having a hollow body of generally circular cross-section, the injector having a powered ram operable to move axially along a segment of a line projecting through the opening;

providing a replaceable syringe formed of a cylindrical body having an axis, a hollow interior within the tubular body, a plunger axially slidable in the interior, and closed forward end having a fluid discharge orifice therein;

the body of the syringe being inserted in the opening with the axis thereof parallel to the line, and locked, around a peripheral rim thereof, to the injector around the opening, the plunger being coupled to the ram, and the syringe being structurally capable of withstanding, at least from the peripheral rim to the orifice, fluid at an operating pressure of at least 100 psi within the interior thereof;

providing linkage relating the angular orientation, about its axis, of the syringe in the opening of the injector and the transverse position of the ram relative to the line; then,

driving the ram forward along the line to move the plunger axially forward at a programmed speed to inject the fluid at the operating pressure through the orifice at a programmed rate into an animal;

imparting to the syringe a releasing motion, relative to the injector, to rotate the syringe about the axis and thereby unlock the syringe from the injector and to transversely translate the syringe relative to the ram and thereby uncouple the plunger from the ram; and then,

removing the syringe from the injector by generally forward axial movement of the syringe relative to the opening.

21. The method of claim **20** further comprising the steps of:

inserting a replacement syringe into the opening of the injector by rearward translatory motion; and

simultaneous with the locking of the syringe to the injector, coupling the plunger to the ram by a motion that is the opposite of the imparted releasing motion.

22. A method of replacing a first syringe with a second syringe in a power injector for injecting fluid into an animal, the method comprising the steps of:

providing the injector with an opening at the front thereof and a power driven ram extendable along a line through the opening;

providing a first syringe positioned in the opening, locked to the injector and having a plunger therein coupled to the ram;

completing the injection of fluid into an animal by extending the ram in a programmed manner to force fluid at a pressure of at least 100 psi from the first syringe at a programmed rate;

disconnecting the plunger of the first syringe from the ram while the ram is substantially extended;

unlocking the first syringe from the injector while the ram is substantially extended;

removing the first syringe from the injector by generally forward translatory movement of the first syringe relative to the opening while the ram is substantially extended;

inserting a second syringe into the injector, by generally rearward translatory movement of the second syringe, back end first, into the opening;

locking the second syringe to the injector; and

coupling the ram to a plunger of the second syringe.

23. The method of claim **22** wherein:

the second syringe inserting step is performed while the ram is substantially extended.

24. A method of loading a replacement syringe into a high pressure power injector for injecting fluid into an animal,

wherein the injector has a forwardly extending tubular pressure jacket having an internal space dimensioned to surround and provide pressure restraining support to the body of a syringe positioned in the jacket, a powered ram, and a motor linked to the ram and operable to move the ram at least partially along a line that extends through internal space of the jacket, and

wherein the replacement syringe has a generally tubular body of generally circular cross-section dimensioned to fit in the internal space of the pressure jacket with its external surface in contact with the pressure jacket, the tubular body having a hollow interior, a plunger longitudinally slidable in the tubular body, a rearward end and forward end having a fluid discharge orifice therein,

the method comprising the steps of:

providing the jacket with a generally circular open front end configured to receive the back end of the syringe; and,

providing the syringe with a peripheral rim located near the forward end of the syringe, the syringe being structurally capable of containing, at least from the peripheral rim to the orifice, fluid at an operating pressure of at least 100 psi within the interior thereof; then,

inserting the syringe into the open front end of the jacket, by generally rearward longitudinal movement relative thereto, so that the syringe body, at least from the rearward end to the peripheral rim thereof, is in the internal space of the jacket; then,

rotating the syringe in the jacket to thereby lock the syringe at the peripheral rim thereof to the injector at the front end of the jacket; and,

coupling the plunger to the ram; and then,

energizing the motor and thereby driving the ram forward along the line and into the hollow interior of the syringe to move the plunger forward in a programmed manner to inject fluid at the operating pressure through the orifice at a programmed rate into the animal.

25. The method of claim **24** further comprising the steps of:

providing linkage interconnecting the rotating and coupling steps;

imparting to the syringe a releasing motion to rotate the syringe relative to the jacket and thereby unlock the syringe from the injector and to uncouple the plunger from the ram; and

removing the syringe from the injector by generally forward axial movement of the syringe from the jacket.

26. The method of claim **25** wherein:

the motion imparting step includes the step of translating the plunger transversely relative to the ram to uncouple the plunger from the ram in a motion linked to the rotation of the syringe relative to the jacket.

27. The method of claim 24 wherein:

the locking of the syringe body to the injector includes the step of threading the peripheral rim of the syringe to the jacket around the opening.

28. The method of claim 24 wherein:

the syringe rotating step and the plunger coupling step are performed simultaneously.

29. The method of claim 24 wherein:

the coupling of the plunger to the ram occurs upon the performance of the syringe rotating step.

30. The method of claim 24 further comprising the step of:

after coupling the plunger to the ram and before the step of energizing the motor and thereby driving the ram forward, retracting the ram and thereby rearwardly moving the plunger and thereby drawing fluid into the second syringe.

31. A method of loading an empty syringe into a power injector for injecting fluid into an animal and for filling the syringe with the fluid to be so injected, the syringe having a tubular body with a hollow interior therein, an open rearward end communicating with the hollow interior, and a closed forward end having a discharge orifice therethrough, the syringe having a plunger moveable in the hollow interior between the rearward end and forward end, and wherein the injector has a syringe mount and a power driven ram extendable therefrom, the method comprising the steps of:

securing an empty syringe to the syringe mount of the injector with the plunger in an initial position proximate the forward end of the syringe body;

providing the ram in a forward position extending from the injector, through the rearward end of the body of the syringe and into the hollow interior thereof;

coupling the ram, while in the forward position in the hollow interior of the syringe body, to the plunger while the plunger is in its initial position proximate the forward end of the tubular syringe body;

connecting a supply of fluid to the discharge orifice; and,

energizing a ram drive to translate the coupled ram rearwardly from the forward position to thereby move the plunger rearwardly in the body to draw fluid into the interior of the syringe through the orifice from the connected supply.

32. The method of claim 31 wherein:

the syringe mount of the injector has syringe-receiving structure supported by the injector, the power driven ram being extendable through the syringe-receiving structure;

the method further comprises the step of translating the rearward end of the syringe toward and into the syringe-receiving structure; and,

the securing step includes the step of locking the syringe to the syringe-receiving structure while the rearward end of the syringe is in the syringe receiving structure.

33. The method of claim 31 further comprising the steps of:

after drawing fluid into the interior of the syringe body, disconnecting the supply from the orifice;

thereafter, connecting a tube between the orifice and the animal; and,

then energizing the ram drive to translate the ram forwardly in a programmed motion to thereby translate the plunger of the syringe forwardly to inject a programmed flow of fluid from the hollow interior of the body of the syringe, through the orifice and the tube connected thereto, into the animal.

34. The method of claim 31 wherein:

the syringe mount of the injector has syringe-receiving structure supported by the injector, the power driven ram being extendable through the syringe-receiving structure;

the method further comprises the step of translating the rearward end of the syringe longitudinally rearwardly, toward the syringe-receiving structure, while the ram is in the forward position and before securing the syringe to the syringe mount of the injector; and

the securing step includes the step of locking the syringe to the syringe-receiving structure.

35. The method of claim 31 further comprising the step of:

loading the syringe onto the injector while the ram is in the forward position and before securing the syringe to the syringe mount of the injector.

36. A method of loading an empty syringe into a power injector for injecting fluid into an animal and for filling the syringe with the fluid to be so injected, the syringe having a tubular body with a hollow interior therein, an open rearward end communicating with the hollow interior, and a closed forward end having a discharge orifice therethrough, the syringe having a plunger moveable in the hollow interior between the rearward end and forward end, and wherein the injector has a syringe mount and a power driven ram extendable therefrom, the method comprising the steps of:

providing the ram in a forward position extending from the injector, through the rearward end of the body of the syringe and into the hollow interior thereof;

securing an empty syringe to the syringe mount of the injector with the ram in its forward position;

coupling the ram to the plunger while the ram is in its forward position;

connecting a supply of fluid to the discharge orifice;

energizing a ram drive to translate the coupled ram rearwardly from the forward position to thereby move the plunger rearwardly in the body to draw fluid into the interior of the syringe through the orifice from the connected supply.

37. The method of claim 36 wherein:

the coupling step includes the step of coupling the ram to the plunger within the hollow interior of the tube while the plunger is remote from the open rearward end of the tubular body.

* * * * *

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. : 5,456,669
DATED : October 10, 1995
INVENTOR(S) : Charles Neer, et al.

It is certified that error appears in the above-indentified patent and that said Letters Patent is hereby corrected as shown below:

In the claims:

In claim 19, column 16, line 60, "the and" should be deleted and --the orifice and-- should be inserted.

In claim 20, column 17, line 28, "line" should read as --axis--.

Signed and Sealed this
Twentieth Day of August, 1996

Attest:

BRUCE LEHMAN

Attesting Officer

Commissioner of Patents and Trademarks

US005658261A

United States Patent [19]

Neer et al.

[11] Patent Number: 5,658,261

[45] Date of Patent: *Aug. 19, 1997

[54] **DISPOSABLE FRONT LOADABLE SYRINGE**

[75] Inventors: **Charles Neer**, Milford; **Frank M. Fago**, Mason, both of Ohio; **Paul E. Dieterlen**, Covington, Ky.; **James H. Goethel**, Cincinnati, Ohio

[73] Assignee: **Liebel-Flarsheim Company**, Cincinnati, Ohio

[*] Notice: The term of this patent shall not extend beyond the expiration date of Pat. No. 5,279,569.

[21] Appl. No.: **417,823**

[22] Filed: **Apr. 6, 1995**

Related U.S. Application Data

[62] Division of Ser. No. 195,382, Feb. 14, 1994, Pat. No. 5,451,211, which is a continuation of Ser. No. 712,110, Jun. 7, 1991, Pat. No. 5,300,031.

[51] **Int. Cl.**[6] **A61M 5/00**

[52] **U.S. Cl.** **604/240**; 604/154; 604/218; 128/DIG. 1; 128/655

[58] **Field of Search** 604/154, 232, 604/155, 241, 242, 131, 151, 152, 187, 218, 228, 240; 128/DIG. 1, 654, 655; 222/326, 327, 390

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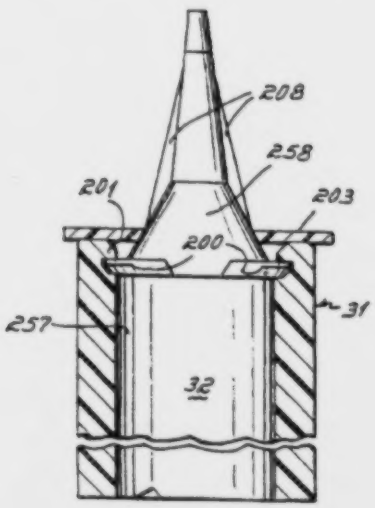
Primary Examiner—Corrine M. McDermott
Assistant Examiner—Ronald K. Stright, Jr.
Attorney, Agent, or Firm—Wood, Herron & Evans, L.L.P.

[57] **ABSTRACT**

An animal fluid injector, replaceable syringe and method of replacement of the syringe in the injector are provided in which the syringe is loadable and unloadable into and from the injector through the open front end of a pressure jacket of the injector, thereby permitting replacement without retraction of the syringe plunger drive or disconnection of the injection tubing. The syringe is provided with a pressure restraining front end, such as an integral or removable cap with structure such as threads that lock the syringe to the front end of the jacket by mating with threads on the jacket. A mechanism in the injector, which includes, for example, a key on cam ring operated by a lever with one hand of an operator, interacts with structure such as symmetrically spaced notches on the back end of the syringe to, for example, rotate the syringe and simultaneously translate or rotate a coupling on the syringe plunger into and out of engagement with the plunger drive in the injector.

37 Claims, 11 Drawing Sheets



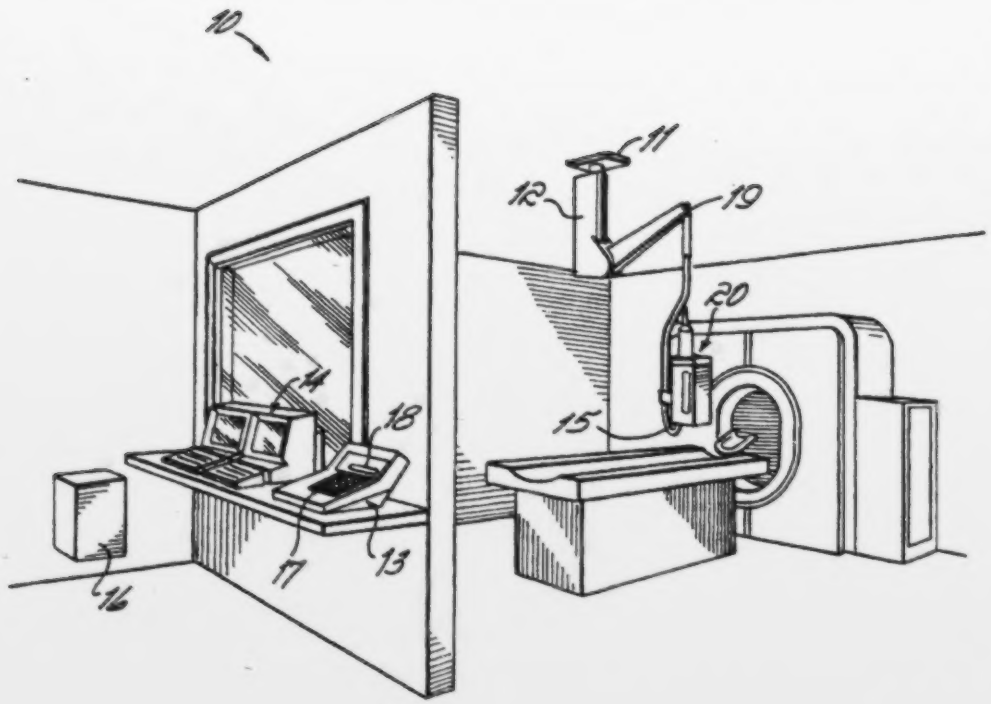


FIG. 1

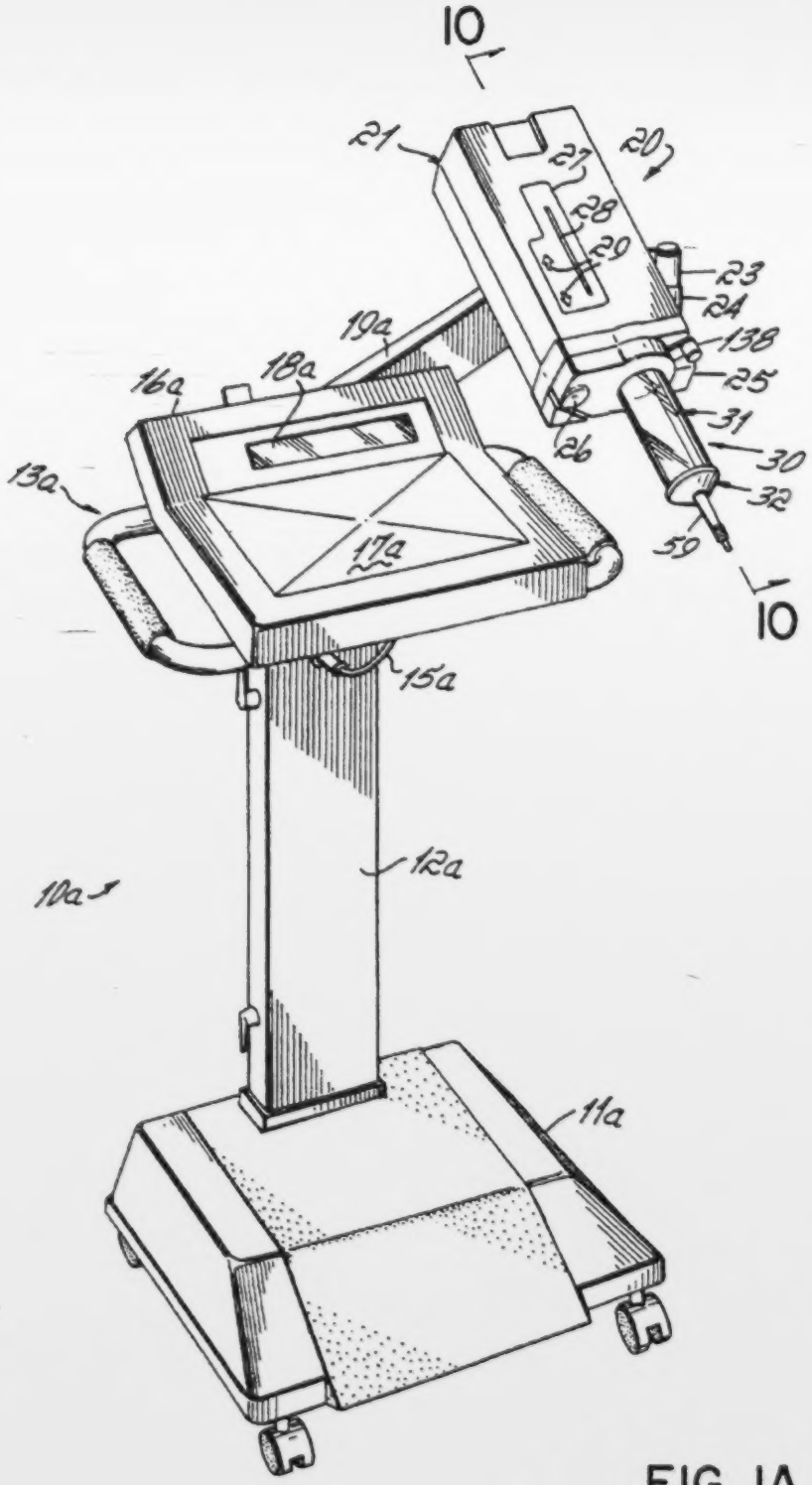

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FIG. 1A

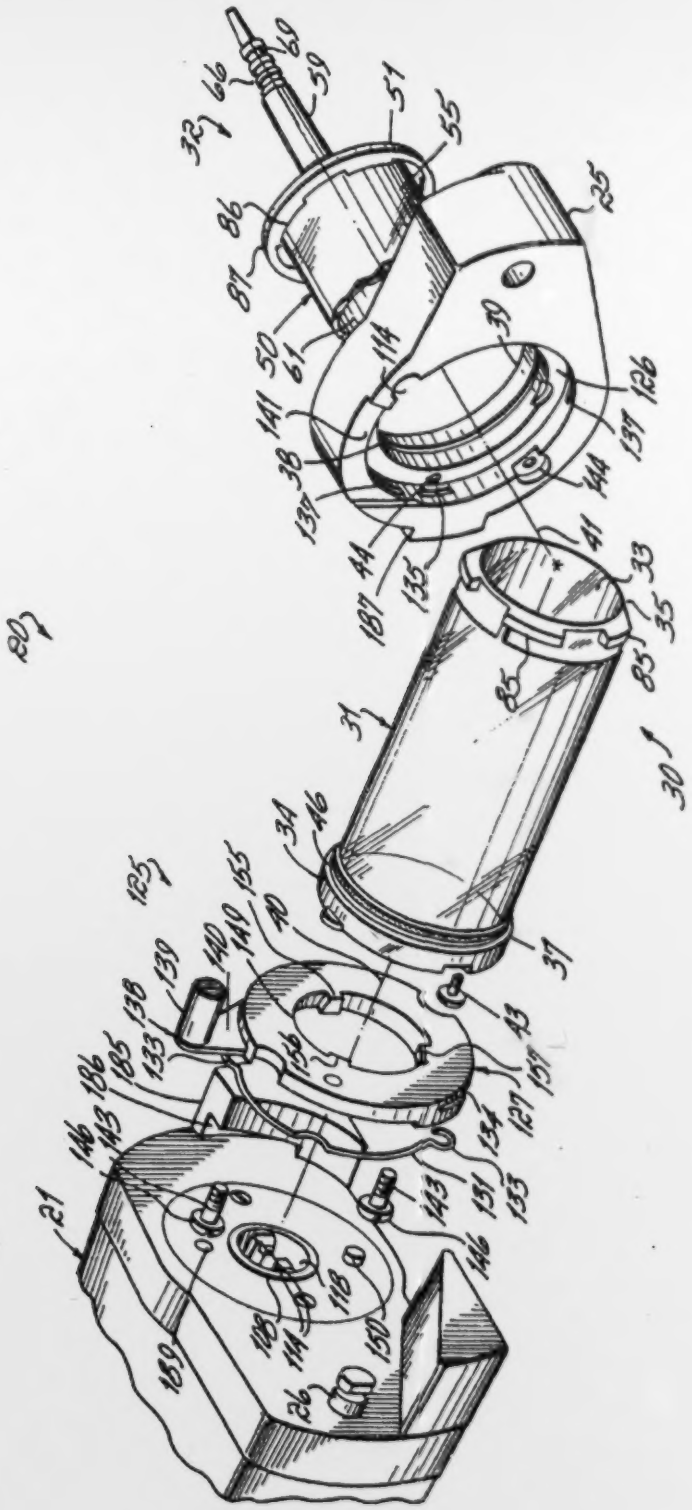
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FIG. 2

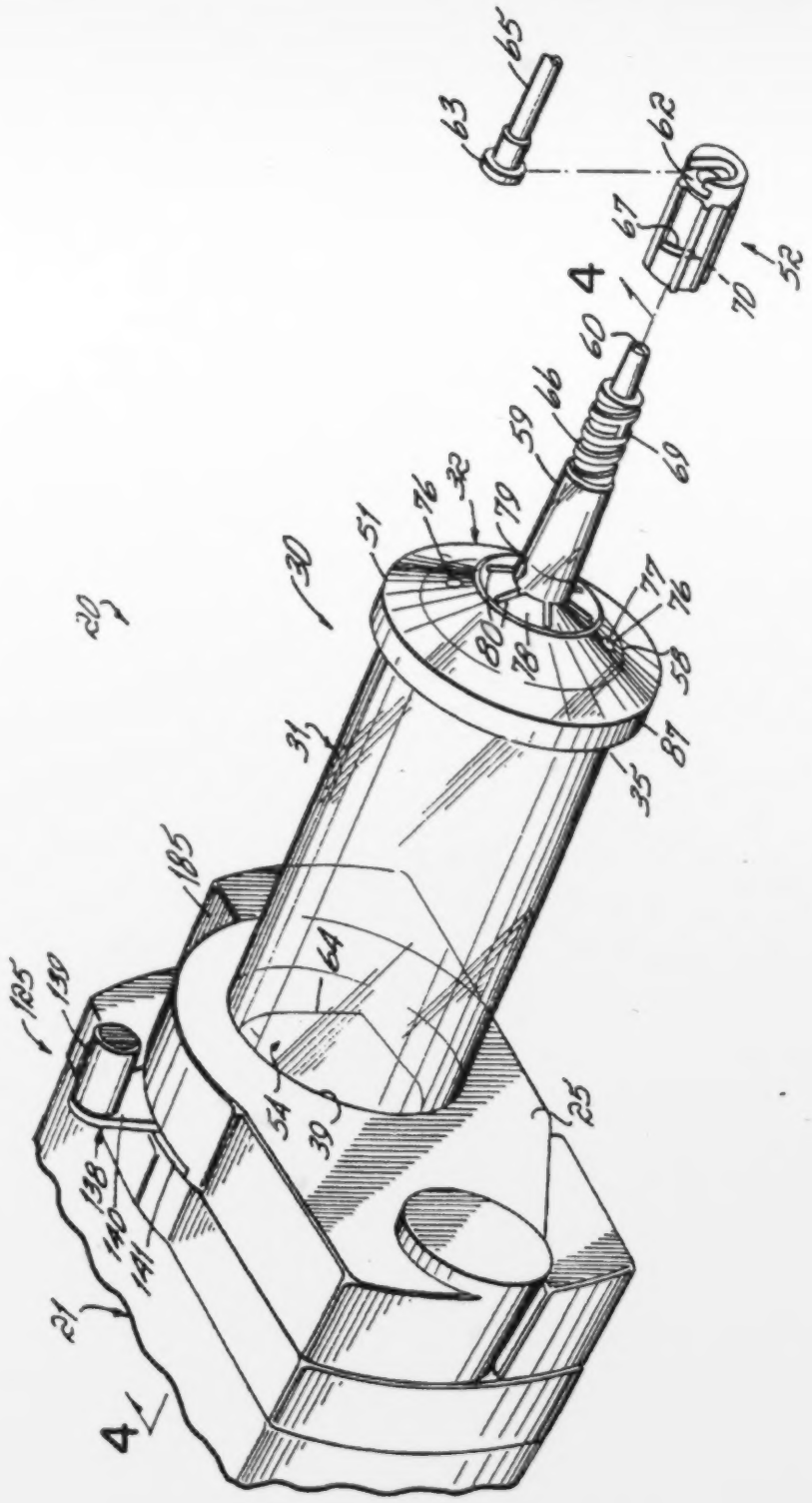
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FIG. 3

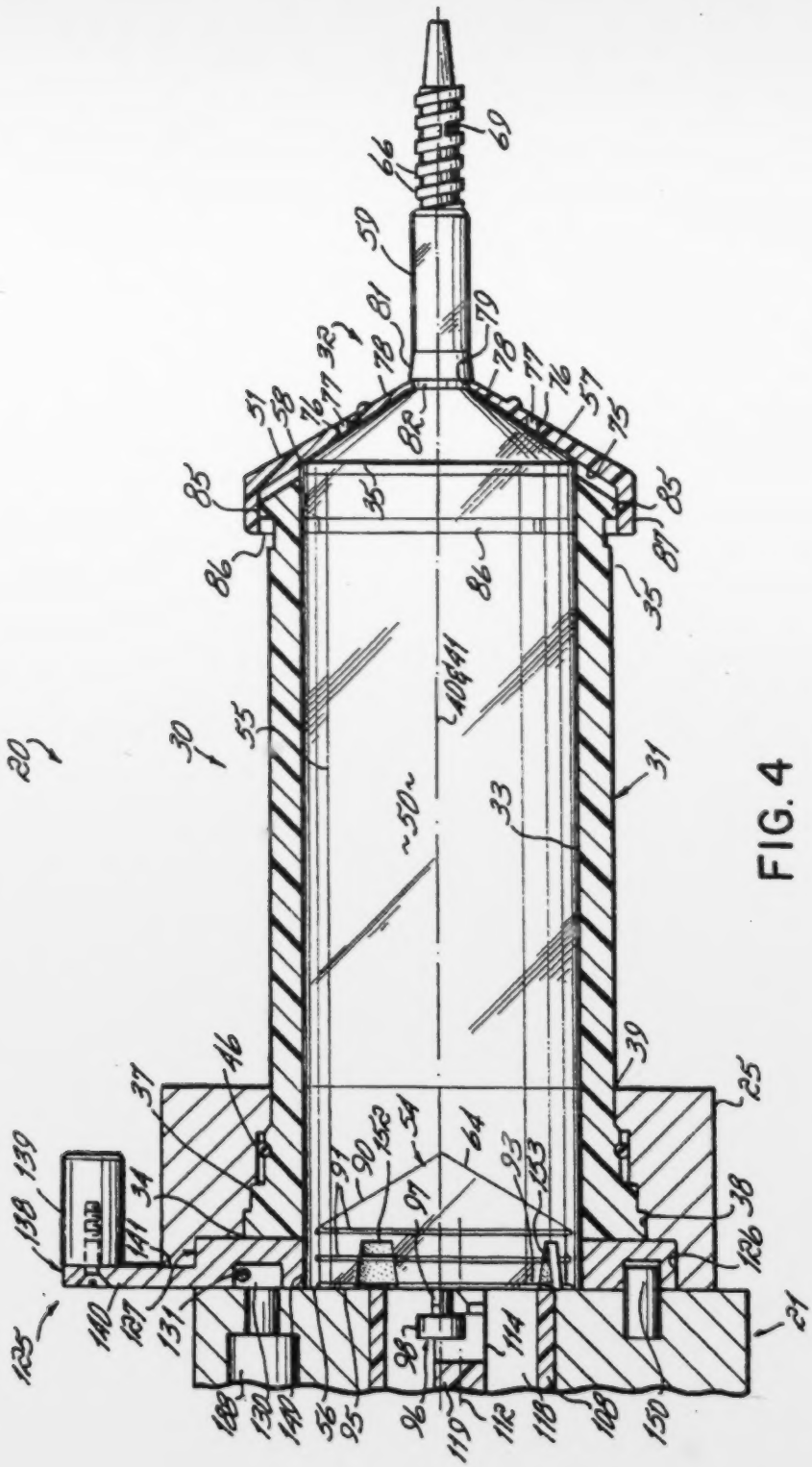

FIG. 4

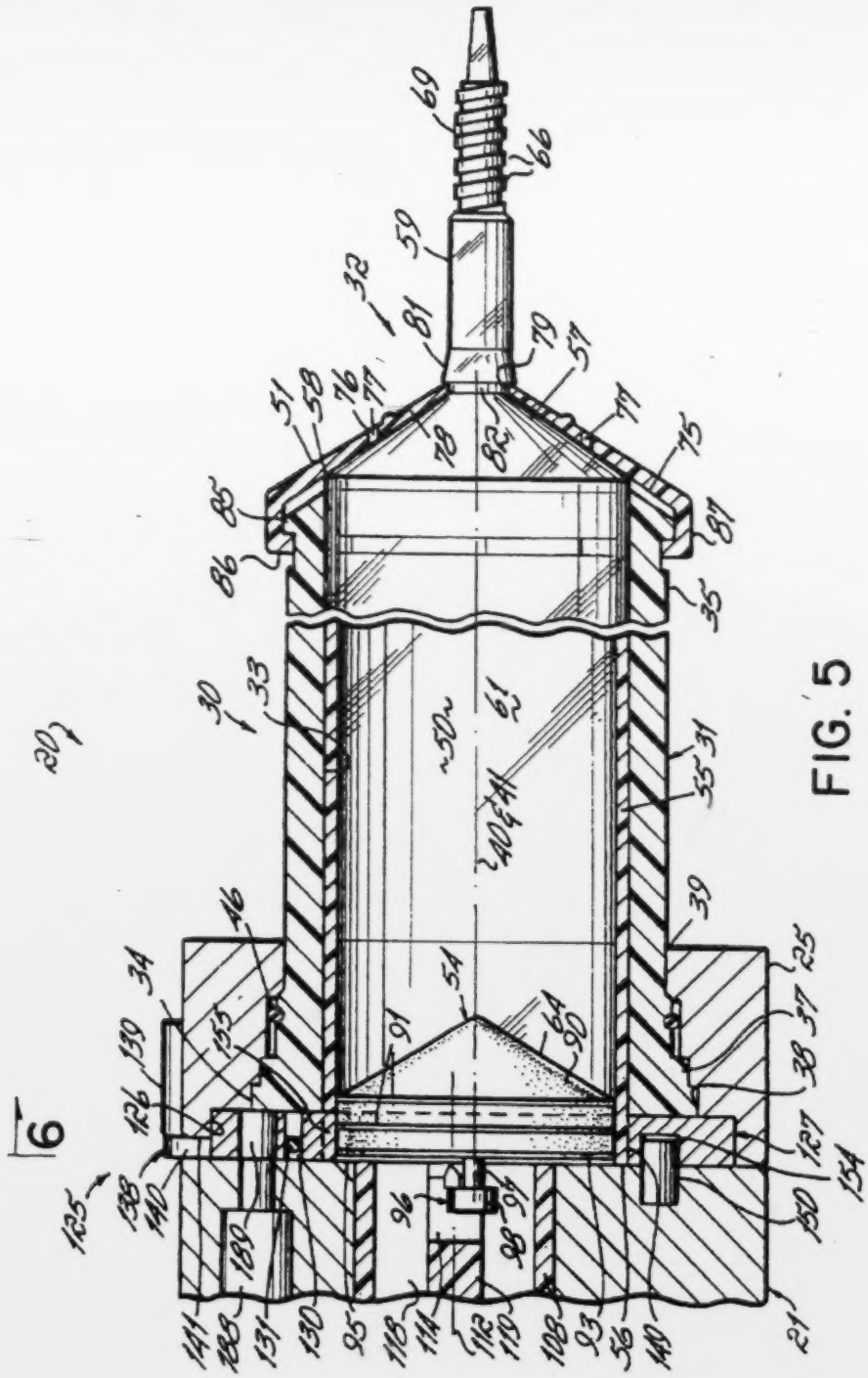
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FIG. 5

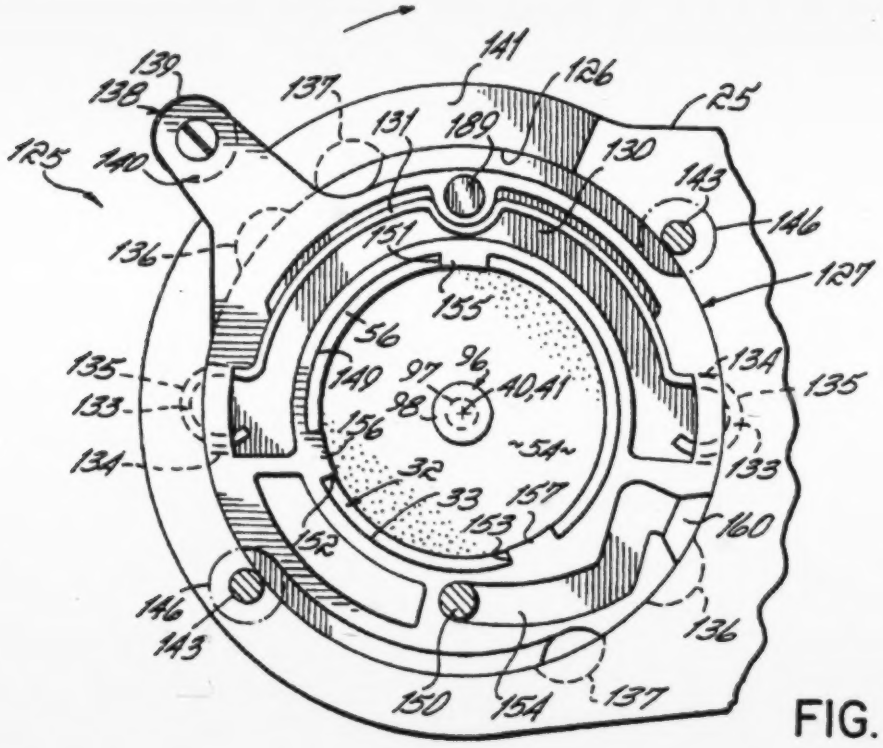

FIG. 6

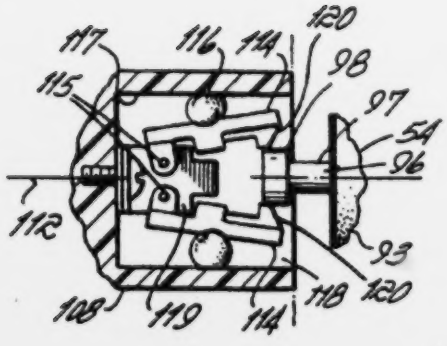

FIG. 11

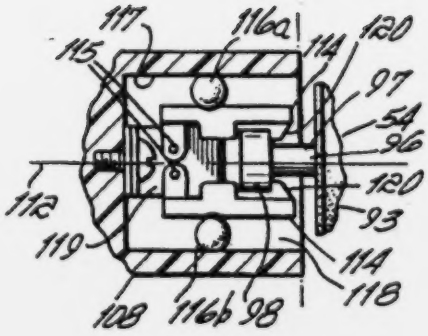

FIG. 12

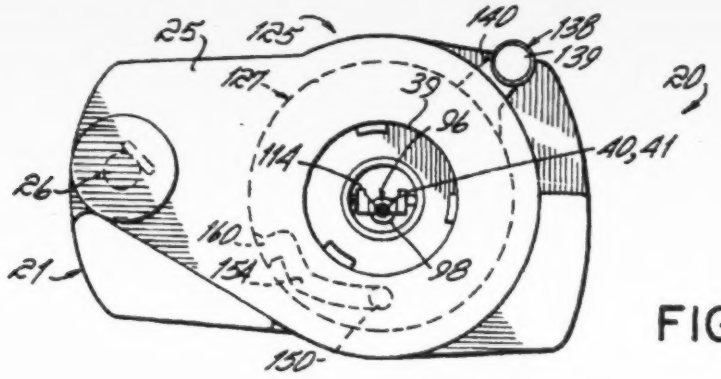

FIG. 7

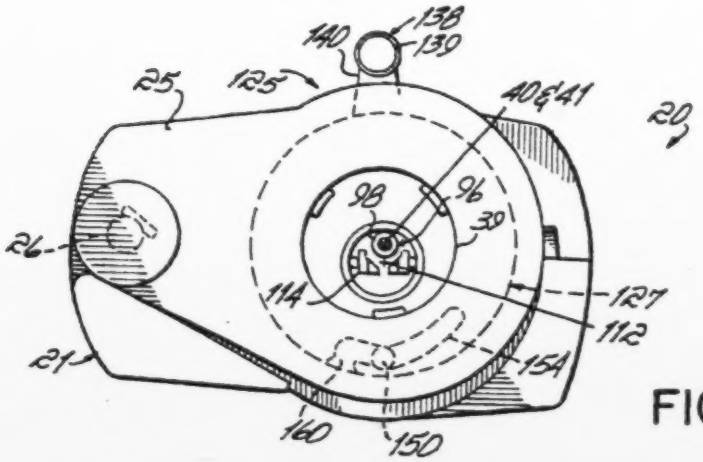

FIG. 8

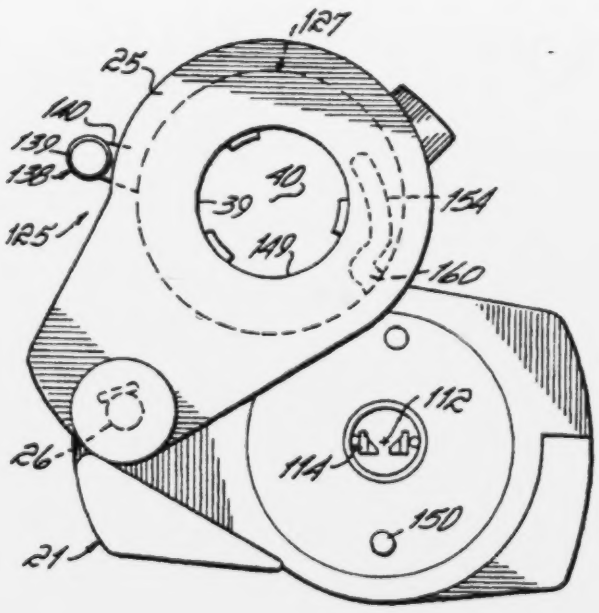

FIG. 9

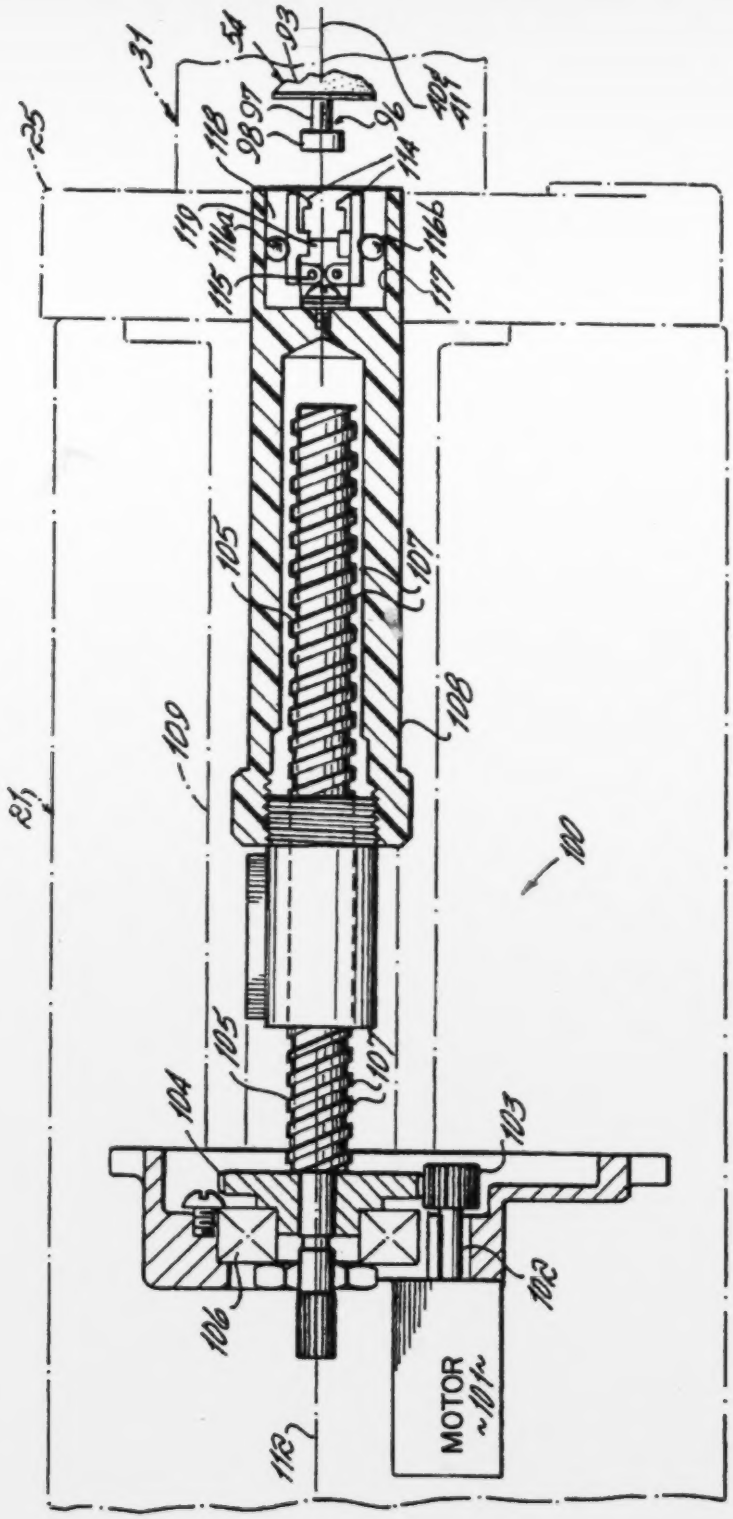

FIG. 10

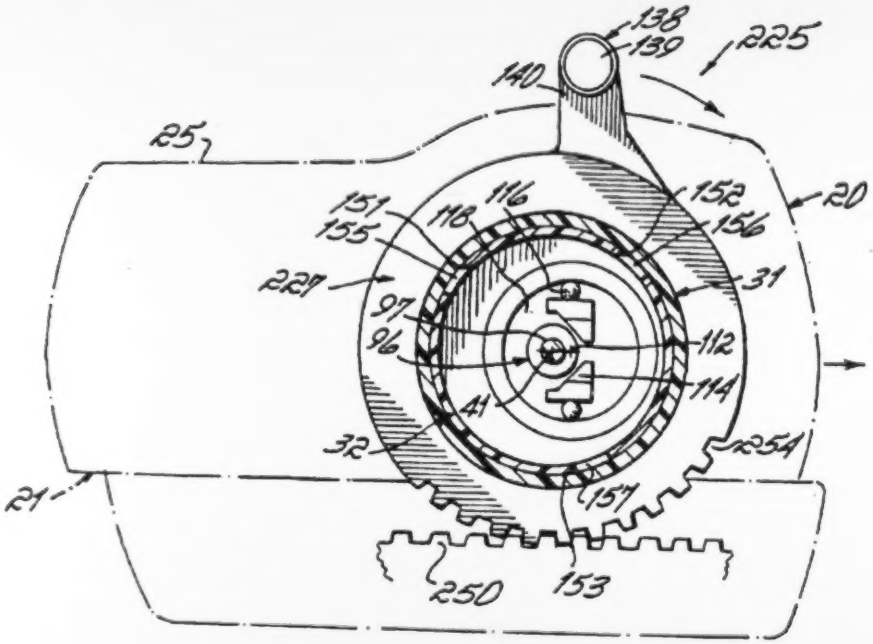
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FIG. 13

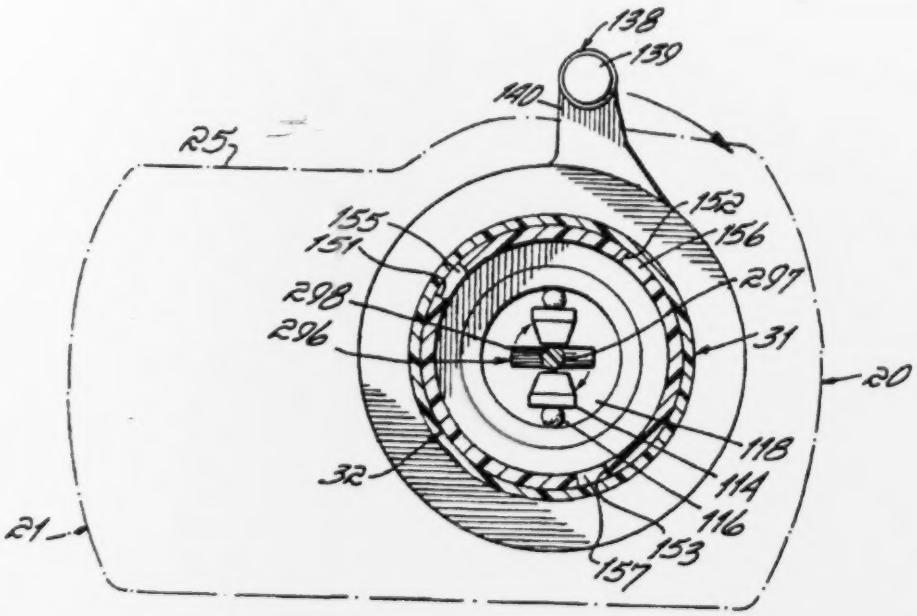
138
139
140
25
155
151
152
156
298
297
296
31
20
118
32
114
116
153
157
21

FIG. 14

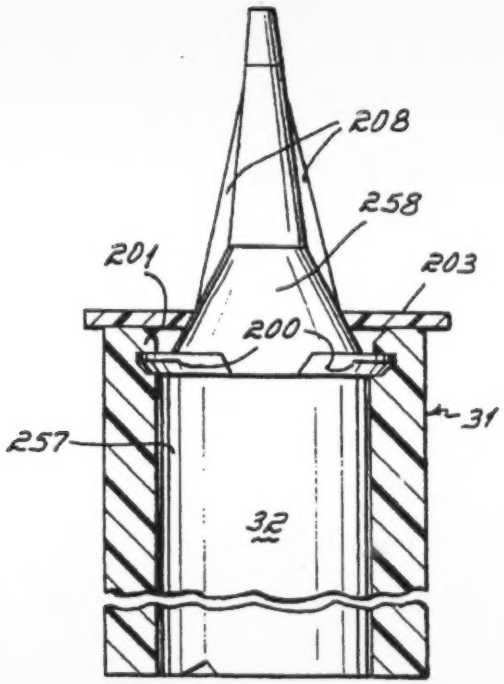

FIG. 15

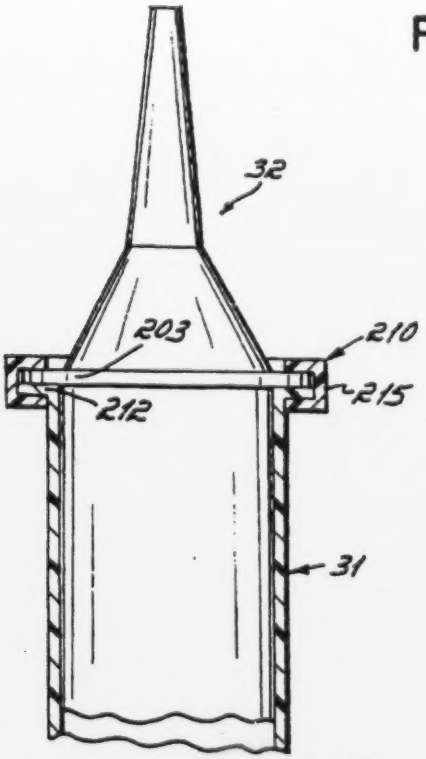

FIG. 16

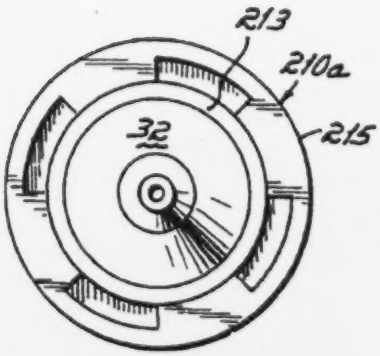

FIG. 17

DISPOSABLE FRONT LOADABLE SYRINGE

This is a divisional of application Ser. No. 08/195,382, filed Feb. 14, 1994, now U.S. Pat. No. 5,451,211 of application Ser. No. 07/712,110, filed Jun. 7, 1991, now U.S. Pat. No. 5,300,031.

FIELD OF THE INVENTION

The present invention relates to injectors and more particularly to disposable replacement syringes for animal fluid injectors.

BACKGROUND OF THE INVENTION

Injectors are devices that expel fluid, such as contrasting media, from a syringe and through a tube into an animal. The injectors are provided with an injector unit, usually adjustably fixed to a stand or support, having a drive that couples to the plunger of the syringe to drive it forward to expel fluid into the tube, or that may be driven rearward to draw fluid into the syringe to fill it. Usually the syringe is a disposable replacement type.

In the injection phase where the plunger is driven forward, pressures are developed in the syringe that range from, for example, twenty-five psi for some applications to over 1000 to 1200 psi for other applications. Syringes that will contain fluid under such pressures are expensive and therefore impractical where the syringes are to be disposable. Accordingly, many such injectors, such as angiographic injectors, for example, have been provided with pressure jackets fixed to the injector units and into which the syringes are inserted. The pressure jackets contact the outer surfaces of the syringe to restrain the walls of the syringe against the internal pressures.

To hold the syringes in the pressure jackets, the jackets of the prior art have been configured to surround the front ends of the syringes to restrain the syringe front wall against forward acting forces of the drive and the fluid pressure and to hold the syringe in the jacket. Because the front end of the pressure jacket is closed, rear loading was necessary, and accessibility thereto was provided by hinging or rotating the jacket to allow for removal and replacement of the syringe from the rear. The opening and reclosing of the injector unit to replace the syringe requires a certain amount of time, which, in the course of the procedure being performed, is not wholly desirable.

Furthermore, while for many years injector units of various types have been capable of disconnection of the plunger drive from the drive coupling on the syringe plunger at any position of the plunger within the syringe, retraction of the drive is typically required before the syringe can be removed. This is because the opening of the injector unit to remove and insert the syringe from the rear requires, for example, a translating or rotating of the jacket from the axis of the drive, which cannot be achieved if the plunger drive is extended.

For example, at the end of an injection procedure, the syringe plunger typically is forward, as is the plunger drive. Since, in the prior art injectors that load from the rear, the pressure jacket is moved through the position that the drive occupies when extended in order to remove the syringe. Hence, the syringe cannot be immediately removed without retracting the plunger drive. Further, the disposable tubing that connects to the nozzle of the syringe must be disconnected from the syringe in order to remove the syringe from the jacket. Additionally, when an empty new syringe is inserted, the drive must be in its retracted position.

More often than not, the syringe is inserted empty and filled by retraction of the plunger with an injection tube connected to a supply of the fluid that is to be injected. In addition, before an empty new syringe can be filled it is necessary that the plunger be fully forward in the syringe so that the syringe can be filled by rearward retraction of the plunger. As a consequence of the need with such prior art injectors to retract the drive upon loading the syringe, it is then necessary to fully advance the drive to the position in which it is in engagement with the plunger and the plunger is in its full forward position. The drive then engages a coupling on the plunger of the replacement syringe. This need to retract and advance the drive contributes to a loss of time in the syringe replacement process.

Accordingly, there has been a need to more quickly load and unload disposable replacement syringes in angiographic injectors, and for injectors and replacement syringes that can accommodate a more efficient process of syringe replacement.

SUMMARY OF THE INVENTION

It is an objective of the present invention to provide a method and apparatus by which replaceable syringes can be more efficiently loaded into and unloaded from injectors.

It is a more particular objective of the present invention to provide an injector, more particularly an angiographic injector, a replacement syringe therefor, and a method of replacing the syringe in the injector that provide for more efficient replacement of the syringes in the injector. It is an additional objective of the present invention to provide an injector wherein a used syringe can be removed and a new one inserted in the injector without retraction of the drive from the pressure jacket, in most applications. It is a further objective of the invention to allow for the removal of the used syringe from the jacket without disconnection of the injector tube from the syringe nozzle.

It is still a further objective of the present invention to provide an injector, replaceable syringe and method of syringe replacement with which the replacement of the syringe can be achieved with simple motions by the operator or with rapid operation of injector unit mechanisms.

An additional objective of the present invention is to provide an injector and replaceable syringe therefor that will facilitate control of the orientation of the syringe in the jacket, and thereby provide for positive, rapid and reliable engagement of the syringe with locking structure that holds the syringe in the jacket, engagement of the plunger drive and plunger drive coupling, or connection of the injection tube to the outlet of the syringe.

A further objective of the present invention is to provide for easy to operate mechanism and reliable locking structure for locking the syringe in place in the pressure jacket of the injection unit.

Another objective of the present invention is to provide an injector and syringe arrangement that minimizes or eliminates the probability of spillage from the syringe nozzle flowing into the injector equipment, and otherwise enhancing the ability to maintain sterility and cleanliness of the equipment.

According to the principles of the present invention, there is provided an angiographic injector having a front end loadable syringe that can be loaded into and removed from the injector pressure jacket through an opening that is provided in the front end of the pressure jacket. To provide this front end loadable feature, the syringes of the preferred and illustrated embodiments of the present invention are

provided with a front wall that is pressure restraining, that is, is of sufficient strength to support the front of the syringe against the expected pressures within the syringe, and that is securable to the front end of the pressure jacket so as to complete the pressure restraining enclosure of the syringe within the pressure jacket and hold the syringe in the jacket. In one preferred form, this front end of the injector is formed of a separate pressure restraining cap made of material that is separate from the front wall of the syringe and may be reusable. In another preferred form, the cap may be formed integrally of the front syringe wall. With the cooperating structure of the jacket and the syringe, restraining of the pressure jacket along the front and sides of the syringe is provided where the jacket allows for the replacement of the syringe from the front.

In one preferred and illustrated embodiment of the invention, the front end of the syringe locks to the front end of the pressure jacket through a cooperating engagement of mating threads on the syringe jacket. The threads include external thread sections formed at the front end of the pressure jacket and internal threads formed on an outwardly extending flange or rim of the front wall of the syringe, preferable on a pressure restraining cap. Alternatively, other securing or locking structure such as a clip or an adaptor, for example, may be employed to join the syringe to the jacket.

In the preferred embodiment of the present invention, the threads are engageable in a limited number of angular positions to thereby predetermine the angular orientation of the syringe in the pressure jacket. Additionally, other keys and keyways carried respectively by the unit and by the syringe limit the angular position in which the syringe may be inserted into the jacket to a unique predetermined angular orientation. Preferably, three keyways, such as slots or notches, unequally spaced around the back, rearward or proximate edge of the syringe body, engage similarly spaced keys or tabs on the unit at the rear end of the pressure jacket to permit insertion of the syringe into the jacket in one and only one orientation.

Further in accordance with principles of the present invention, in its preferred embodiment, a coupling on the syringe plunger is centrally located and symmetrical about the axis of the plunger. A pair of jaws on the plunger drive is moveable either by transverse straight or arcuate translatory motion or by forward longitudinal motion to form a connection between the coupling and the drive. Once coupled to the drive, the coupling remains engaged to the drive during longitudinal motion of the drive to cause the plunger to move forward or backward with the drive. Disengagement occurs thereafter only upon transverse translational motion of the plunger with respect to the drive. In certain embodiments, this translatory transverse motion occurs by translatory movement of the jacket, and the injector unit door that carries the jacket, with respect to the plunger drive and the unit housing. In other embodiments, an asymmetrical coupling is provided that engages and disengages the plunger drive upon rotational movement of the syringe with respect to the drive.

Preferably, the motion for locking the syringe to, and unlocking the syringe from, the jacket is achieved by rotation of the syringe in the jacket, and preferably, this motion is linked to, and occurs simultaneous with, the motion that engages and disengages the plunger coupling and drive, whether that coupling is by translation or rotation. In addition, the syringe and plunger drive are so dimensioned and positioned to prevent contact between the drive and the sterile interior wall of the syringe, regardless of the position of the drive, as the syringe is being loaded.

Preferably, the syringe is formed of a cylindrical body, with the front end in the shape of a truncated cone that terminates in a forwardly extending neck with an orifice at its remote end that is connectable with an injection tube. The front end of the syringe is shaped so as to direct fluid leaking from the nozzle outwardly around the front end of the jacket. This prevents leakage, which often results upon disconnection of the injection tubing, from entering the space between the pressure jacket and the syringe body.

Replacement of the syringe begins, in the preferred embodiments of the invention, with unlocking the syringe at its front end from the front end of the pressure jacket, preferably by rotating the syringe with respect to the jacket, and by disengaging the plunger drive from the syringe plunger, alternatively by transverse translational or rotational motion, preferably simultaneous with and linked to the motion that disengages the syringe from the jacket. The unlocking of the syringe from the jacket occurs, for example, by loosening mating threads at the front of the syringe and jacket. The twisting of the syringe in the jacket is linked to motion that either translates transversely or rotates a coupling on the syringe plunger out of engagement with the plunger drive.

Then the syringe is removed from the jacket through the open front end of the jacket. This removal may take place without retraction of the plunger drive, should the drive be advanced in the pressure jacket at the time of disengagement from the plunger coupling. The used syringe may also be removed without disconnection of the disposable injection tubing from the nozzle of the syringe.

When the used syringe is removed, a replacement syringe is inserted into the jacket through its open forward end and the front end of the new syringe is locked to the front end of the jacket, preferably by relative rotation of the syringe in the jacket to cause, for example, engagement between mating threads on the front end of the syringe and the front end of the jacket. The plunger drive, in one embodiment, is translated to bring the plunger coupling engaging jaws into alignment with the plunger coupling, preferably simultaneously with the locking of the syringe to the jacket. The jaws thereby either engage the coupling upon the translatory motion, or thereafter engage the coupling by longitudinal advancement of the drive against the coupling. In one embodiment, the jaws are positioned off center of the drive so that the drive, whether in the engaging or the disengaging positions, does not contact a syringe as the syringe is guided by the jacket during loading.

In an alternative embodiment, engagement of the plunger drive with the coupling occurs by relative rotation of the drive and the coupling, preferably by rotating the coupling relative to a stationary plunger drive, rather than by translational motion between the drive and the coupling. Only if the rest position of the plunger of the replacement syringe is behind the final position of the plunger drive at the time it was disconnected from the coupling of the plunger of the syringe being replaced need the plunger drive be retracted.

The engagement and disengagement motions between the plunger drive and plunger drive coupling, and between the syringe and the pressure jacket, are provided with manually operable mechanism that, in the preferred and illustrated embodiments, rotates the syringe in the jacket and further either rotates or translates the coupling with respect to the plunger drive, with a simple one hand operated mechanism. The mechanism provides a convenient lever, operable through a short arc, to rotate the syringe in the jacket and to then, preferably, translate the pressure jacket that carries the

syringe and is carried by the injector unit door, or to otherwise move the syringe with respect to the drive, to bring the plunger coupling of the syringe into or out of alignment with the plunger drive.

The present invention provides a disposable syringe that may be replaced in an angiographic or CT injector with great efficiency and speed. Further, replacement may occur without retraction of the plunger drive of the injector unit. Simple and rapid one hand operation of the engaging and disengaging structure is provided.

These and other objectives of the present invention will be more readily apparent from the following detailed description of the drawings in which:

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a perspective view of an angiographic CT injector embodying principles of the present invention.

FIG. 1A is a perspective view of an another form of angiographic injector embodying principles of the present invention.

FIG. 2 is an exploded perspective view of a portion of one preferred embodiment of the injector of FIG. 1.

FIG. 3 is a perspective view of the portion of the injector of FIG. 2.

FIG. 4 is a cross-sectional view along lines 4—4 of FIG. 3 illustrating a replaceable syringe unlocked from the housing for insertion into or removal therefrom.

FIG. 5 is a cross-sectional view similar to FIG. 4 but illustrating the syringe locked to the structure carried by the housing.

FIG. 6 is a cross-sectional view along the line 6—6 of FIG. 5.

FIG. 7 is an elevational diagrammatic illustration of the injector of FIG. 1 with the pressure jacket and syringe removed, and showing the syringe locking structure in the locked position such as in FIGS. 5 and 6.

FIG. 8 is an elevational diagrammatic view similar to FIG. 7 illustrating the syringe locking structure in the unlocked position such as in FIGS. 2–4.

FIG. 9 is an elevational diagrammatic view similar to FIG. 7 illustrating the locking mechanism in the housing door release position.

FIG. 10 is a cross-sectional view through the housing of the injector taken along lines 10—10 of FIG. 1A with the plunger drive disengaged from the syringe plunger coupling.

FIG. 11 is a view of a portion of FIG. 10 illustrating the plunger drive longitudinally moving into engagement with the plunger coupling.

FIG. 12 is a view of a portion of FIG. 10 illustrating the plunger drive in engagement with the plunger coupling.

FIG. 13 is a front view of a portion of another embodiment of the injector of FIG. 1.

FIG. 14 is a view of an alternative embodiment of a portion of a syringe according to principles of the present invention.

FIG. 15 is a cross-sectional view similar to FIG. 5 of an alternative embodiment of the invention, illustrating alternative engaging structure between the front ends of the syringe and jacket.

FIG. 16 is a cross-sectional view similar to FIG. 5 of a further alternative embodiment of the invention, also illustrating alternative engaging structure between the front ends of the syringe and jacket.

FIG. 17 is a front end view of still a further alternative embodiment of the invention, also illustrating alternative engaging structure between the front ends of the syringe and jacket.

DETAILED DESCRIPTION OF THE DRAWINGS

Referring to FIG. 1, an angiographic injector 10 according to another preferred embodiment of the present invention is illustrated, configured for CT applications. The injector 10 includes a ceiling mounted support 11, adjacent a CT X-ray unit, to the lower surface of which is rigidly supported a vertically descending support column 12.

Remote from the support 11 is an injector control module console 13 behind a wall which isolates the operator area from the X-ray equipment. The console 13 is located adjacent a control 14 of the X-ray equipment. Electrical power and control cables (not shown) communicate power and control signals through the support 11 and the column 12 and to a power lead 15. The console 13 connects with an injector control module 16, which includes a programmable microprocessor (not shown) to which commands and programming codes are input through a keyboard 17 on the console 13. The console 13 is also provided with an operator display 18 to aid in interfacing the input commands and injector status with the operator.

Attached to the column 12 is an articulating adjustable arm 19. To the remote end of the arm 19 is adjustably supported injection module unit 20. The arm 19 is capable of setting the unit 20 at varying positions adjacent a patient bed of the CT unit.

Referring to FIG. 1A, an angiographic injector 10a according to another preferred embodiment of the present invention is illustrated. The injector 10a includes a wheeled base 11a to the top of which is rigidly supported a vertically adjustable upstanding support column 12a. To the top of the column 12a is supported a control module platform 13a. Electrical power is communicated from a power cord (not shown) through the base 11a and the upstanding support 12a and through a power lead 15a to a control module 16a rigidly supported to the platform 13a. The control module 16a includes a programmable microprocessor (not shown) to which commands and programming codes are input through a keyboard 17a on the module 16a. The module 16a is also provided with an operator display 18a to aid in interfacing the input commands and injector status with the operator. Attached to the platform 13a is an articulating adjustable arm 19a. To the remote end of the arm 19a is adjustably supported the injection module unit 20.

The injection module unit 20 of the embodiments of FIGS. 1 and 1A includes a housing 21 which contains the operating drive structure of the injector 10 or 10a. The housing 21 has a support bracket 23 fixed thereto and adjustably pivotally supported to the remote end 24 of the articulating arm 19 or 19a. The housing 21 has pivotally attached to the front thereof a door 25 at the front thereof which is pivotally connected to the housing 21 at a longitudinally extending pivot or hinge pin 26 (FIG. 2) rigidly supported on the housing 21 and extending forwardly from the front of the housing 21.

On the top of the housing 21 is an injector position and local control panel 27 having a position indicator scale 28 thereon, which displays the position of the injector drive to the operator. The panel 27 also includes a pair of forward and reverse drive direction control buttons 29, which are selectively actuatable to activate a drive within the housing 21 in either the forward or reverse directions.

Extending forwardly from the front of the door 25 is an injector syringe and pressure jacket assembly 30, the structure of which can be better understood with reference to FIGS. 2–5 below. The syringe and jacket assembly 30 includes a hard plastic pressure jacket 31, which may be of opaque or transparent material, a removable and replaceable disposable syringe 32, which may be of opaque, transparent or semi-transparent material, and related structure hereinafter described.

The syringe 32 is disposable, and includes walls which will withstand only moderate or low pressure. The walls are usually outwardly deformable under operating pressures, particularly pressures of 300 psi or more. Such higher pressures are necessary to overcome pressure drops through the injection tubing at higher flow rates, which are often desirable. The jacket 31 is made of a stronger transparent material that will withstand the operating pressures. When the syringe 32 is contained in the jacket 31, it is surrounded by the jacket 31 and supported by the jacket 31 against expansion caused by the fluid pressure within as the syringe 32 expands against the jacket wall.

The pressure jacket 31 has a generally cylindrical inner bore 33 extending therethrough from a proximate end 34 adjacent the door 25 to a remote end 35 of the pressure jacket 31 toward the front of the unit 20. The bore 33 is dimensioned so as to receive through the remote end 35 the disposable syringe 32 and to support the syringe against expansion from fluid pressure within such fluid pressure may range to more than a thousand psi. The pressure jacket 31 has an annular flange 37 extending outwardly around the proximate end 34. The flange 37 is integrally formed with the jacket cylinder and is shaped to conform to an annular recess 38 surrounding a circular hole 39 in the door 25 to which the jacket 31 may be assembled by insertion from the rear. The hole or opening 39 in the door 25 and the cylindrical bore 33 of the jacket 31 are concentric with a longitudinal axis 40 on which also lies an axis 41 of the syringe 32 when the syringe 32 is positioned in the bore 33 of the jacket 31. The jacket 31 is firmly and rigidly attached to the door 25 with a pair of screws 43, only one of which is shown, which are threaded into a pair of holes 44 in the back of the door 25 (FIG. 2). An O-ring seal 46 surrounds the flange 37 of the jacket 31 in the recess 38 of the door 25.

The syringe 32 includes a syringe case 50 formed of a single piece of molded plastic material, a pressure cap 51, a tubing collar 52 (FIG. 3) and a plunger 54 (FIGS. 3–5). The syringe case 50 includes a cylindrical syringe body 55 having an open proximate end 56 and a remote end 58 to which is integrally formed a conical front wall 57. The front wall 57 is truncated at its forward end, to which is integrally formed an elongated neck 59 extending from the wall 57 at the center thereof. The neck 59 of the syringe case 50 has an orifice 60 (FIG. 3) in its remote end which communicates with an internal syringe cavity 61 formed within the neck 59, the conical front wall 57 and the cylindrical body 55 of the case 50 of the syringe 32. The rear end of the cavity 61 is further defined by a forward facing conical surface 64 of the plunger 54. The conical surface 64 is of a slope which conforms to the slope of the interior of the conical front wall 57. The plunger 54 is slidable within the body 55 of the syringe case 50 such that the cavity 61 is of variable volume.

Near the front end of the neck 59 of the syringe case 50, just behind the orifice 60, is an external thread 66 configured to mate with threads 67 on the interior of collar 52 (FIG. 3). The thread 66 in the neck 59 has a stop 69 at near forward end thereof to engage an abrupt step 70 on the thread 67 of the collar 52 so that, when the syringe 32 is properly oriented in the jacket 31, the collar 52, when loosened to its maximum extent, will assume a predetermined orientation so as to present, in an upwardly facing orientation, a tube end receiving slot 62 formed in the remote end of the collar 52. This slot 62 is of T-shaped cross-section so as to receive the enlarged flange end 63 of a tube 65 through which fluid from the syringe cavity 61 is injected into a patient.

The cap 51 is generally conical in shape and has an inner rearward surface 75, which conforms to the front surface of the conical wall 57 of the case 50 of the syringe 32. In certain embodiments, the rearward conical surface 75 of the cap 51 may be bonded to the front surface of the conical wall 57 of the case 50 of the syringe 32, or it may be formed integrally therewith, molded from the same plastic material as the case 50 of the syringe 32. In the preferred and illustrated embodiment, the cap 51 is separate from the syringe body portion 55 and has a pair of holes or detents 76 into which fit a pair of projections 77 extending forwardly from and formed integrally on the outer surface of the conical wall 57 of the case 50 of the syringe 32. The cooperation of the pins or projections 77 with the holes or detents 76 prevent the cap from rotating with respect to the syringe case 50 when the cap 51 is mounted on the syringe 32.

To hold the cap 51 against the conical wall 57 of the case 50 of the syringe 32, six resilient tabs 78 are formed about a central inner hole 79 of the cap 51. The tabs 78 are separated by six equally spaced radial slots 80 (FIG. 3). The hole 79 in the cap 51 is equal to or only slightly greater in size than the circular forward end of the conical wall 57 of the case 50 of the syringe 32. The neck 59 of the syringe 32 has an enlarged straight section 81 slightly greater in diameter than the hole 79 in the cap 51 and also greater in diameter than the forward end of the conical wall 57 of the case 50, thereby forming a groove 82 at the juncture of the straight neck portion 81 with the conical wall 57 so that the tips of the tabs 78, which are sufficiently resilient to slide over the enlarged neck portion 81 as the cap 51 is inserted on the case 50 of the syringe 32 with the hole 79 surrounding the neck 59 to snap fit into the groove 82.

The syringe 32 includes structure that is configured to lock the syringe 32 to the front end of the jacket 31 by cooperating with mating structure on the jacket 31. The jacket 31 has, spaced around the circumference thereof near the remote or front end 35 of the jacket 31, four equally spaced outwardly projecting thread sections 85. These thread sections 85 are slightly less than 45° in extension around the circumference of the jacket 31 and are spaced apart with gaps of slightly greater than 45°. The cap 51 has a cylindrical rim 87 in which are formed four similarly sized and spaced mating thread sections 86. The thread sections 86 project inwardly toward the jacket 31 when the syringe 32 is positioned in the jacket 31. As such, when the syringe 32, with the cap 51 assembled to it is inserted into the jacket 31, the threads 86 of the cap 51 pass through the spaces between the threads 85 on the jacket 31 to a point behind the threads 85. When so inserted, the syringe assembly 32 with the cap 51 may be twisted clockwise 45° to tighten and thereby secure the cap 51 to the jacket 31 by engagement between the threads 85 and 86 as shown in FIG. 5, to thereby lock the syringe in the bore 33.

The piston 54 of the syringe 32 is molded of an elastomeric material. Preferably, the piston 54 includes two portions molded of different materials and bonded together. These portions include a forward more flexible portion 90 in which is formed the forward conical surface 64. This forward portion 90 has a pair of outwardly extending rings 91 formed in the periphery thereof to make sealing engagement

with the inside of the wall of the cylindrical body **55** of the syringe case **50**. The rearward portion of the piston **54** is a flat circular surface to which is bonded the flat circular forward surface of a more rigid rear portion **93** of the piston **54**. The rear rigid portion **93** of the piston **54** is molded of a harder stronger plastic material and has a rearward facing circular surface **95** having a rearward extending coupling **96** integrally formed thereon at its center. The coupling **96** includes a rearwardly extending cylindrical shaft **97** on the axis **41** of the syringe **32** and a larger symmetrical cylindrical button **98** integrally formed at the rear end of the cylindrical shaft **97**.

Referring to FIG. **10**, a piston drive assembly **100** is illustrated contained within the housing **21**. The drive assembly **100** includes an electric motor **101** mounted within the fixed housing **21** and having a rotary output shaft **102** with a drive gear **103** fixed to the remote end thereof. The drive gear **103** is positioned for driving engagement with a driven gear **104** fixed near the rear end of a drive screw or shaft **105** supported at its rear end in a bearing **106** fixed in the housing **21**. The screw or shaft **105** has a continuous external helical thread **107** thereon which mates with interior threads of a carriage **108**. The carriage **108** is slidably supported in a bushing **109** fixed in the housing **21**. The shaft **105** rotates within the housing **21** about a longitudinal axis **112**.

At the forward end of the carriage **108** is supported a pair of hooked jaws **114** which are pivotally mounted at their rearward ends by a pair of pivot pins **115** to the carriage **108**. The jaws **114** are biased toward the axis **112** by a pair of balls **116***a* and **116***b* of resilient material positioned between the outside of the jaws **114** and an inner cylindrical wall **117** of a recess **118** formed in the forward end of the carriage **108**. The balls **116***a*, **116***b* are partially captured in depressions in the outer surfaces of the jaws **114**. The balls **116***a*, **116***b* bias the jaws toward their innermost position toward the axis **112**. The innermost position of the jaws is determined by a spacing block **119** on the axis **112** of the carriage **108** at the center of the cavity **118**.

When a syringe **32** is locked in the jacket **31** with its axis **41** and the axis **40** of the jacket **31** may be in alignment with the axis **112** of the shaft **105**, the plunger **54** may be located in the cylindrical body **55** of the syringe case **50** in a position forward of the remote end **56**. Preferably, however, the jaws **114** are displaced to the side of axis **112** of the shaft **105** so that as the jaws **114** and coupling tip **98** are in their disengagement position, maximum clearance is provided so that the syringe **32** may be inserted into the jacket **31** without the sterile internal walls of the syringe **31** touching the components of the drive, as illustrated in the figures.

In the engaging position, the jaws **114** are nonetheless in alignment with the coupling **98** on the axes **40** and **41** of the jacket **31** and syringe **32**. In such a situation, the jaws **114** may be in a retracted position at the center of the opening **39** of the door **25** adjacent to the proximate end **34** of the jacket **31**, and out of engagement with the coupling **96** on the plunger **54**. From this position, operation of the motor **101** rotates the shaft **105** and drives the carriage **108** forwardly to move the jaws **114** toward and into engagement with the coupling **96** on the plunger **54**. This engagement takes place as shown in FIG. **11** where a pair of tapered cam surfaces **120** at the forward interface of the tips of the jaws **114** engage the enlarged portion or button **98** of the coupling **96** to expand the jaws, as shown in FIG. **11**, to snap around the button **98** of the coupling **96** to form a driving engagement between the drive assembly **100** and the coupling **96** of the plunger **54** as shown in FIG. **12**. Once so engaged, any forward or reverse movement of the carriage **108** under the power of the motor **101** will cause the plunger **54** to be driven either forwardly or backwardly in the syringe body **55**.

Disengagement of the jaws **114** from the coupling **96** can thereafter be achieved by translational movement between the coupling **96** and the jaws **114** between a disengaged position as shown in FIG. **4** and an engaged position as shown in FIG. **5**. When the plunger coupling **96** and the jaws **114** are disengaged, the syringe **32** can be replaced without the need to retract the carriage **108** of the drive **100**. This allows for rapid replacement of the syringe **32**. Preferably, the jaws **114** are either fully retracted toward the housing **21** where engagement by translation of the coupling **96** will occur, or the jaws **114** are sufficiently within the jacket prior to replacement of the syringe so that the coupling **96** of the replacement syringe **32** will not contact the jaws **114** except as the drive **100** is advanced.

If sterility is not a problem, the most time saving approach would be to insert the syringe **32** into the jacket **31** with its plunger all the way forward and the drive fully advanced so that, when the syringe is translated toward the jaws **114**, engagement will immediately occur and the plunger can be immediately retracted to fill the syringe.

When a syringe **32** is inserted into the jacket **31** when the plunger **54** is at its rearmost position toward the proximate end **56** of the syringe body **55**, the coupling **96** is in a position adjacent the proximate end **56** of the syringe body **55** and projecting rearwardly therebeyond. When in such a position, engagement between the jaws and the coupling **96** is brought about by translational movement between the position shown in FIG. **4** and that shown in FIG. **5**. In the unlocked or disengaged position shown in FIG. **4**, the axes **40** and **41** of the jacket **31** and the syringe **32**, respectively, as well as the center of the opening **39** of the door **25**, lie spaced from and parallel to the axis **112** of the shaft **105** as shown in FIG. **4**. In the locked or engaged position, the axis **112** of the shaft **105** is slightly eccentric relative to the axes **40** and **41** of the jacket **31** and syringe **32**, respectively, as shown in FIG. **5**. This translational movement, the engagement and disengagement between the coupling **96** and the jaws **114** and the 45° rotational movement which secures the cap **51** to the pressure jacket **31** by engagement of the threads **85** and **86** are brought about by operation of a translating and locking mechanism **125**, which is best understood by reference to FIGS. **2–9**.

The translating and locking mechanism **125** includes a cam and locking ring **127** which is rotatably retained in a circular recess **126** in the back of the door **25**. The ring **127** has a generally semi-circular groove **130** in the back surface thereof for receiving a spring wire retaining clip **131** having a pair of looped ends **133** which extend through a pair of slots **134** in the rim of the ring **127** and into a selected one of three pair of diametrically opposed notches **135**, **136** and **137** in the inner wall of the rim of the recess **126** in the door **25**. The three pair of notches **135**, **136** and **137** represent three positions of the translating and locking mechanism **125** which are the locked, unlocked and release positions, respectively. The locked position of the mechanism **125** in which the loops **133** of the ring **131** are in the notches **135**, is that illustrated in FIGS. **5–7** and **10**. The unlocked position, in which the loops **133** of the ring **131** are in the notches **136**, is that illustrated in FIGS. **2–4** and **8**. The release position, in which the loops **135** of the clip **133** are in notches **137**, is that illustrated in FIG. **9**. The ring **127** is moved among these three positions by a manually accessible handle **138** in the form of a cylindrical knob **139** rotatably

attached to a lever arm 140 formed integrally and extending radially from the ring 127 through a slot 141 in the door 25 (FIG. 2). The ring 127 is retained in the recess 126 by a pair of screws 143 which thread into countersunk holes 144 at the periphery of the recess 126 in the back of the door 25. These screws 143 have enlarged heads 146, which, when seated in the holes 144, overlie the edge of the ring 127, thereby securing it for rotatable movement within the recess 126.

As shown in FIGS. 2 and 6, the ring 127 has an inner periphery 149 which is larger than the circumference of the body 55 of the syringe case 50. Accordingly, when the syringe 32 is inserted in the jacket 31, the proximate end 56 of the syringe case 50 extends through and is surrounded by the inner periphery 149 of the ring 127. Asymmetric keyway structure, preferably in the form of three slots or notches 151, 152 and 153 (FIG. 6) are provided in the edge of the proximate end 56 of the body 55 of the syringe case 50. The spacings between adjacent pairs of the notches 151–153 differ from each other. Formed integrally of the ring 127 and projecting inwardly from the inner periphery 149 thereof are three tabs or keys 155, 156 and 157. These tabs 155–157 are spaced so as to fit into the respective notches 151–153 in the proximate end 56 of the body 55 of the syringe case 50 so as to rotate the syringe 32 as the mechanism 125 is rotated through actuation of the handle 138. Because the notches 151–153 and the tabs 155–157 are unequally spaced, they can only engage each other when the syringe 32 is inserted into the jacket 31 in one and only one orientation. That orientation is one which will cause the slot 62 of the collar 52 (FIG. 3) to align 45° counterclockwise of the vertical when the mechanism 125 is in its unlocked position, which is a position in which it will be when the syringe is first inserted into the jacket 31, and to be in an upwardly facing orientation, when fully loosened, when the mechanism 125 is moved to its locked position. Accordingly, the notches 135 and 136 in the recess 126, which receive the loops 133 of the spring clip 131 when respectively in the locked and unlocked positions, are 45° apart.

The rotation of the mechanism 125 from the unlocked position to the locked position rotates the syringe 32 in the jacket 31 and rotates the cap such that its threads move from an unlocked position as shown in FIG. 4 to the locked position of FIG. 5, to secure the cap to the jacket 31 by the engagement and tightening of the threads 85 and 86.

The translational movement of the axes 40 and 41 with respect to the axis 112 is achieved by a fixed cylindrical cam follower or pin 150 which projects outwardly from the fixed housing portion 22 behind the ring 127 and into a cam slot 154 formed therein. The slot 154 is shaped so that the axes 40 and 41 which remain fixed with respect to the ring 127, along with the door 25, the jacket 31, the syringe 32 and all of the structure mutually carried thereby, are moved in relation to the axis 112 of the shaft 105 and the other structure mutually carried by the housing 21, as the mechanism 125 is rotated. These axes move toward and away from each other in accordance with the shape of the slot 154 determined by the radial distance from the point along the slot 154 where it engages the pin 150 to the axes 40 and 41.

The cam slot 154 in the ring 127 is shaped such that, when the mechanism 125 is in the locked position as shown, for example, in FIGS. 6 and 7, the distance between the pin 150 and the axes 40 and 41 is at a minimum and the axis 112 coincides with the axes 40 and 41. This is illustrated in FIGS. 5 and 7 wherein the coupling 96 is shown positioned between the jaws 114 and in mutual engagement therewith. When the mechanism 125 is in the unlocked position, with the loops 133 of clip 131 in the notches 135 (FIG. 6) of the recess 126, the pin 150 lies in the slot 154 in the position shown in FIG. 8, which is farther displaced from the axes 40 and 41 than in the position of FIGS. 6 and 7, so that the coupling 96 is translated to a position outside of the center line of the jaws 114, as shown in FIG. 8 and further illustrated in FIG. 4.

In the release position, as shown in FIG. 9, the pin 150 is positioned at the open end 160 of the cam surface of the slot 154 so that the door 25 can be rotated upwardly about the hinge pin 26, as shown in FIG. 9, to open the space behind the door 25 for access thereto. This position may be used for cleaning the area behind the door 25 which is sometimes necessary because of possible leakage of fluid from the cavity 61 into the space behind the plunger 54. This can possibly occur because the fluid within the cavity 61, when being injected by forward advancement of the plunger 54, may be of relatively high pressure in the range, usually over 200 psi. For applications such as the injection of contrasting fluid for CT scanning, pressure may typically be in the range of from 25 to 300 psi., while in some angiographic injection applications the pressure may range to 1200 psi or higher.

In addition, leakage rearwardly along the exterior of the neck 59 of the syringe 32 can cause fluid to flow between the body portion 55 of the syringe 32 and the jacket 31. For this reason, the cap 51 is caused to fit snugly against the forward surface of the conical portion 57 of the syringe 32 at least sufficiently to restrict the flow of this leaking fluid onto the neck 59. This is assisted by the configuration of the cap 51 at the rim 87 thereof so as to divert away from the space between the syringe 32 and jacket 31 fluid which might leak from the nozzle.

The front of the housing 21 has formed thereon a door stop 185 having a slot 186 formed therein for receiving a lug 187 of the door 25, to restrain the door 25 against forward force exerted by the drive 100. Behind the front of the housing 21 adjacent the stop 185 is a magnetic sensor 188, which is responsive to the presence of a magnet 189 in the lever arm 139 of the handle 138. The sensor 188 generates a signal to the control module 16 to activate the drive 100 only when the mechanism 125 is in its locked position.

Referring to FIG. 13, there is illustrated a locking mechanism 225 that is an alternative to the locking mechanism 125 described above. In the locking mechanism 225, a stationary geared rack 250 is provided fixed to the housing 21. A mating gear segment 254 is formed on the outer rim of the alternative locking ring 227 of this embodiment. The gear segment 254 and rack 250 replace and function in the same way as the slot 154 and pin 150 of the embodiment described above. As the mechanism 225 is rotated by the handle 138, the door 25 that carries the jacket 31 and the syringe 32 is translated to bring the coupling 96 into or out of engagement with the jaws 114 of the drive 100. Simultaneous with this translatory motion, the syringe 32 is rotated in the jacket 31 to lock or unlock the syringe 32 to the jacket 31 by engagement or disengagement of the threads 86 on the syringe 32 with the threads 85 on the jacket 32.

FIG. 14 illustrates an alternative to the embodiment of the coupling 96 described above. In the embodiment of FIG. 14, there is provided a coupling 296 that is T-shaped, having a rectangular endpiece 298 at the rearward end of a cylindrical or square shaft 297 on the rearwardly facing circular surface 95 of the plunger 54. Such a coupling 296 engages the jaws 114 by rotation of the locking mechanism 125 or 225, preferably through an angle of 90°. When the orientation of the endpiece 298 is parallel to the plane of the jaws 114, the drive 100 is locked to the plunger 54 so that axial movement

of the drive **100** moves the plunger axially, in the forward direction to expel fluid form the syringe cavity **61**, or in a rearward direction to fill the cavity **61** with fluid. When the endpiece **298** is perpendicular to the plane of the jaws **114**, the coupling **296** will move into or out of engagement with the jaws **114** upon relative axial movement between the plunger **54** and the drive **100**. Thus, with this embodiment, rotational motion, rather than translational motion, causes engagement and disengagement of the coupling **296** by the jaws **114**. With this embodiment, orientation of the syringe **32**, when loaded into the jacket **31**, is preferably maintained through the cooperation of the notches **151–153** and the tabs **154–156** (FIG. **4**), so that the coupling **296** will enter the jaws **114**, when the syringe **32** is inserted into the jacket **31**, with the endpiece **298** perpendicular to the pair of jaws **114**.

The locking structure between the syringe **32** and the pressure jacket **31** should provide for retention of the syringe **32** in the jacket **31** against the force of the fluid pressure in the cavity **61** or axial force otherwise exerted on the plunger **54** by the drive **100**. This locking of the syringe **32** to the jacket **31** is preferably achieved, as shown in FIG. **5**, by structure at or near the forward wall **57** of the syringe case **50**. In accordance with the embodiment of FIG. **15**, such structure may include external threads **200** formed of four equally spaced, radially outwardly directed thread sections (flanges), each spanning slightly less than 45° about syringe body **257**, and positioned (monolithic with) the forward end of the syringe body **257**, which mate with internal threads **201** formed of four equally spaced, radially inwardly directed mating thread sections (flangs), each spanning slightly less than 45° about jacket **31**, positioned around the opening at the remote end of the tubular cylindrical pressure jacket **31**. With such an embodiment, the syringe **32** is preferably provided with continuous, planar annular ring-shaped flange **203** around (monolithic with) the body **257** at the juncture of the body **257** with the syringe front wall **258**. Threads **200** and **201** form a connector, specifically, a screw or twist lock whereby syringe **32** may be rotated or twisted 45° to lock syringe **32** to the injector. The flange **203** inhibits the flow of leaked fluid into the space between the syringe body **257** and a peripheral rim of the jacket **31**. With such an embodiment, the wall **258** is either thickened, provided with reinforcing such as the ribs **208**, or provided with other structure to resist deformation of the wall **258** under the pressure of the fluid within the cavity **61**.

Alternatively, a reusable split clip **210** may be employed to secure a continuous flange **203** of such a syringe to a continuous flange **212** at the end of the pressure jacket in the embodiment of FIG. **16**. As a further alternative as shown in FIG. **17**, a ring clip **210***a* having an outer rim **215** and rotatably mounted to the jacket **31**, encircles and engages outwardly projecting threads **203***a* of a disk flange **213** formed at the front end of the syringe **32** to engage the jacket in a manner similar to the threads **85** and **86** in the embodiment of FIGS. **2–12** above.

The invention has been described in the context of its preferred embodiments. It will be appreciated by those skilled in the art that variations and alternatives to the embodiments described may be employed without departing from the principles of the present invention. Accordingly, this patent is not intended to be limited except by the scope of the following claims:

We claim:

1. A disposable replacement syringe for a front loadable injector for injecting liquid into an animal, where the injector has a syringe receiving opening on the front thereof and has a plurality of internal sections circumferentially displaced inside the opening, the disposable syringe comprising:

a hollow body having a cylindrical tubular wall, a central longitudinal axis, a closed forward end having a discharge outlet therein, and an open rearward end;

a plunger snugly slidable within the hollow body in direct contact with the inside of the tubular wall and having a rearwardly facing drive engaging coupling thereon;

an annular flange extending outwardly from the hollow body and monolithic therewith, the annular flange lying in a plane perpendicular to the longitudinal axis of the body; and

locking structure spaced longitudinally a fixed distance rearwardly from the annular flange monolithic with and extending radially from the tubular wall of the body a distance smaller than the outward extension of said annular flange, the locking structure being in the form of a plurality of circumferentially spaced radially extending mating sections configured to engage the internal sections inside the opening on the front of the injector to lock the syringe thereto upon the rearward longitudinal insertion of the mating sections through the opening and the partial rotation of the syringe in the opening, and to thereby urge the annular flange against the opening.

2. The disposable replacement syringe of claim **1** for use with an injector having a pressure jacket extending forwardly therefrom, the jacket having a cylindrical bore therein, the opening of the injector being the hollow bore of the jacket, and wherein the internal internal sections are fixedly located on the inside of the jacket, wherein:

the radially extending mating sections of the locking structure comprise mating sections positioned in a plane perpendicular to the axis of the body of the syringe so as to align with the internal sections on the jacket when the syringe is inserted in the jacket and to lock the syringe to the jacket.

3. The disposable replacement syringe of claim **2**, wherein:

the annular flange is in the form of a continuous annular ring surrounding the body; and

the locking structure forms means for sealably urging the annular flange against the jacket when the syringe is locked to the jacket to inhibit leakage of spilled fluid into the injector.

4. The disposable replacement syringe of claim **1**, wherein:

the annular flange extends outwardly from the forward end of the hollow body.

5. The disposable replacement syringe of claim **1**, wherein:

the locking structure extends radially outwardly from the tubular wall adjacent the forward end of the hollow body.

6. The disposable replacement syringe of claim **1**, wherein:

the plurality of radially extending mating sections includes four equally spaced sections lockable to the internal sections upon rotation of 45 degrees about the axis.

7. The disposable replacement syringe of claim **1**, wherein:

the plurality of radially extending mating sections includes four equally spaced sections each spanning not more than 45 degrees about the axis.

8. The syringe of claim **1**, for use with an injector having a tubular member extending forwardly from the front thereof

and having a cylindrical bore therein forming the opening at the front of the injector, the tubular member having a circular front end lying in a plane; and further comprising:

means, including the locking structure, for urging the annular flange rearwardly against the front end of the tubular member.

9. The syringe of claim 1 for use with an injector having a continuous rim surrounding and forming the periphery of the opening, and wherein:

the annular flange is in the form of a continuous annular ring; and

the locking structure urges the annular flange rearwardly against the syringe receiving opening when the syringe is locked to the injector to form a seal with the opening to inhibit leakage of spilled fluid into the injector.

10. The disposable replacement syringe of claim 1, wherein:

the plurality of radially extending mating sections includes spaced thread sections each spanning not more than 45 degrees.

11. A disposable replacement syringe for a front loadable injector for injecting liquid into an animal where the injector has a circular syringe receiving opening therein bounded by a circular annular periphery lying in a plane and syringe-retaining structure spaced a fixed distance rearward of the periphery and positioned relative to the opening to be engageable therethrough, the disposable syringe comprising:

a hollow body having a cylindrical tubular wall, a central longitudinal axis, a closed forward end having a discharge outlet therein, and an open rearward end;

a plunger snugly slidable within the hollow body in direct contact with the inside of the tubular wall and having a rearwardly facing drive engaging coupling thereon;

a planar annular ring surrounding, extending outwardly from and monolithic with the cylindrical tubular wall forward of the rearward end of the body and lying in a plane perpendicular to the longitudinal axis of the body;

the ring having a rearward facing planar annular surface dimensioned to overly the periphery of the opening; and

locking structure monolithic with the tubular wall of the syringe and extending radially therefrom a distance smaller than the outward extension of said annular ring, spaced the fixed distance rearward of the ring and dimensioned to fit through the opening so as to engage the syringe retaining structure of the injector and urge the ring to seal against the periphery of the opening on the injector to inhibit leakage of spilled fluid into the injector.

12. The disposable replacement syringe of claim 11 wherein:

the locking structure is configured to secure the syringe to the injector by engaging the syringe retaining structure on the injector with a twisting motion to sealably urge the ring against the periphery of the circular opening.

13. The disposable replacement syringe of claim 12 wherein:

the locking structure includes a plurality of circumferentially spaced sections configured to engage the syringe retaining structure of the injector around the opening on the injector to lock the syringe thereto upon rearward longitudinal insertion of the syringe into the opening and partial rotational motion of the syringe.

14. The disposable replacement syringe of claim 11 further comprising:

an annular split clip configured to secure the syringe to the injector; and wherein:

the ring has a diameter substantially equal to a diameter of said split clip to facilitate engagement by the split clip to lock the syringe to the injector and to urge the ring against the periphery of the circular opening.

15. A disposable replacement syringe for a front loadable injector having a syringe receiving opening thereon, the disposable syringe comprising:

a hollow body having a cylindrical tubular wall, a central longitudinal axis, a closed forward end having a discharge outlet therein, and an open rearward end;

a plunger snugly slidable within the hollow body in direct contact with the inside of the tubular wall and having a rearwardly facing drive engaging coupling thereon;

a planar annular ring-shaped flange surrounding, monolithic with and extending outwardly from the hollow body and perpendicular to the longitudinal axis of the body; and

a connector monolithic with the body having an outer breadth smaller than the outward extension of said annular ring-shaped flange, spaced longitudinally rearwardly from the annular ring-shaped flange for locking the syringe to the opening on the injector upon the rearward longitudinal insertion of the rearward end of the syringe into the opening and for sealably urging the annular ring-shaped flange rearwardly against the periphery of the opening to inhibit leakage of spilled fluid into the injector.

16. The syringe of claim 15 wherein the connector includes screw threads in the form of a plurality of circumferentially spaced flange sections extending radially outwardly from the tubular wall to cooperate with mating threads on the injector.

17. The syringe of claim 16 wherein:

the screw threads include four flange sections each spanning less than the circumference of the body so as to enable threaded engagement with the mating threads upon 45° rotation of the syringe.

18. A front loadable power injector for injecting liquid into an animal comprising:

an injector having a housing, a syringe receiving opening and a plunger driving ram mounted in the housing and extendable along an axis through the opening;

a syringe having a hollow body having a cylindrical tubular wall, a central longitudinal axis, a closed forward end having a discharge outlet therein, an open rearward end, a plunger snugly slidable within the hollow body in direct contact with the inside of the tubular wall and having a rearwardly facing drive engaging coupling thereon, an annular flange monolithic therewith extending around and outwardly from the hollow body and perpendicular to the longitudinal axis of the body, and locking structure monolithic therewith spaced longitudinally rearwardly from the annular flange and extending radially from the tubular wall of the body a distance smaller than the outward extension of said annular flange;

the locking structure being in the form of a plurality of circumferentially spaced radially extending sections;

the injector having a plurality of circumferentially spaced radially extending mating sections spaced around the opening;

the radially extending sections of the locking structure being sized to fit between the radially extending mating sections at the opening so as to lock the syringe to the injector upon the rearward longitudinal insertion of the radially extending sections of the locking structure into the opening and between the radially extending mating sections at the opening, followed by partial rotation of the syringe in the opening to thereby urge the annular flange against the opening.

19. The injector of claim 18 wherein:

the injector has a pressure jacket extending forwardly from the housing, the jacket having a cylindrical bore therein, the syringe receiving opening of the injector being in the bore of the jacket; and

the mating sections at the opening are fixedly located on the jacket, whereby the radially extending sections of the locking structure lock the syringe to the jacket.

20. The injector of claim 19 further comprising:

means including the locking structure and the mating sections for sealably urging the annular flange against the jacket.

21. The injector of claim 20 wherein:

the jacket has a circular front end lying in a plane; and

the annular flange is sealably urged rearwardly against the front end of the jacket.

22. The injector claim 18 wherein:

the annular flange is in the form of a continuous annular ring lying in a plane and surrounding the hollow body; and

the ring is configured such that, when urged against the opening, a seal is formed to inhibit leakage of spilled fluid into the injector.

23. The injector claim 18 wherein:

the annular flange extends outwardly from the forward end of the hollow body; and

the injector includes a cylindrical member extending forwardly from the injector housing and having a hollow bore therethrough, the syringe receiving opening being at an end of the bore remote from the injector housing.

24. The injector of claim 18 wherein:

the locking structure extends radially outwardly from the tubular wall adjacent the forward end of the hollow body of the syringe.

25. The injector of claim 18 wherein:

the plurality of radially extending sections of the locking structure and the mating sections at the opening each include four equally spaced thread sections; and

the sections are configured to mutually engage upon rotation of the syringe of 45 degrees.

26. The injector of claim 18 wherein:

the plurality of radially extending sections of the locking structure and the mating sections at the opening each include four equally spaced thread sections spanning not more than 45 degrees.

27. The injector of claim 18 wherein:

the injector housing has a tubular member extending forwardly from the front thereof and having a cylindrical bore therein forming the syringe receiving opening;

the tubular member has a circular front end lying in a plane; and

the annular flange is sealably urged rearwardly against the front end of the tubular member.

28. The injector of claim 18 wherein:

the plurality of outwardly extending sections of the locking structure and the plurality of radially extending mating sections at the opening each include equally spaced thread sections; and

the sections are configured to mutually engage upon rotation of the syringe of 45 degrees.

29. The injector of claim 18 wherein:

the plurality of radially extending sections of the locking structure and the plurality of radially extending mating sections at the opening each include equally spaced thread sections spanning not more than 45 degrees.

30. A front loadable injector for injecting liquid into an animal comprising:

an injector housing having a circular syringe receiving opening bounded by a circular annular periphery lying in a plane and syringe retaining structure spaced a fixed distance rearward of the periphery of the opening and positioned relative to the opening to be engagable therethrough;

a plunger driving ram mounted in the housing and extendable along an axis through the opening;

a syringe having a hollow body having a cylindrical tubular wall, a central longitudinal axis, a closed forward end having a discharge outlet therein, an open rearward end, a plunger snugly slidable within the hollow body in direct contact with the inside of the tubular wall and having a rearwardly facing drive engaging coupling thereon, and a planar annular ring surrounding and extending outwardly from the cylindrical tubular wall, spaced forward of the rearward end and lying in a plane perpendicular to the longitudinal axis of the body;

the ring of the syringe being monolithic with the tubular wall of the syringe and having a rearward facing planar annular surface dimensioned to overly the periphery of the opening; and

the syringe having locking structure thereon monolithic with the tubular wall of the syringe and extending radially therefrom a distance smaller than the outward extension of said annular ring, spaced the fixed distance rearward of the ring and dimensioned to fit through the opening so as to engage the syringe retaining structure of the injector and urge the ring rearwardly to seal the syringe against the periphery of the circular opening on the injector to inhibit leakage of spilled fluid into the injector.

31. The injector of claim 30 wherein:

the locking structure on the syringe and the syringe retaining structure on the injector form a twist lock at least partially carried by the syringe and partially by the injector and configured to secure the syringe to the injector and to sealably urge the ring against the periphery of the circular opening.

32. The injector of claim 31 wherein:

the twist lock includes a plurality of circumferentially spaced thread sections including thread sections forming the locking structure on the syringe and mating thread sections forming the syringe retaining structure on the injector, the thread sections of the locking structure being configured to engage the thread sections of the syringe retaining structure inside the syringe receiving opening to lock the syringe to the injector upon rearward longitudinal insertion of the syringe into the opening and rotational motion of the syringe relative to the injector.

33. A front loadable injector for injecting liquid into an animal comprising:

an injector housing having a syringe receiving opening surrounded by a continuous flange;

a plunger driving ram mounted in the housing and extendable on an axis through the opening;

a syringe having a hollow body having a cylindrical tubular wall, a central longitudinal axis, a closed forward end having a discharge outlet therein, an open rearward end, a plunger snugly slidable within the hollow body in direct contact with the inside of the tubular wall and having a rearwardly facing drive engaging coupling thereon, and a planar annular ring surrounding and extending outwardly from the cylindrical tubular wall, spaced forward of the rearward end and lying in a plane perpendicular to the longitudinal axis of the body;

the ring of the syringe being monolithic with the tubular wall of the syringe and having a rearward facing planar annular surface dimensioned to overly the flange that surrounds the opening to seal the syringe against the periphery of the opening on the injector to inhibit leakage of spilled fluid into the injector;

a reusable split clip configured to clip the ring of the syringe to the flange of the injector to secure the syringe to the injector to lock the syringe to the injector and to urge the ring against the flange surrounding the circular opening.

34. A front loadable injector for injecting liquid into an animal comprising:

an injector housing having a syringe receiving opening and a plunger driving ram mounted in the housing and extendable along an axis through the opening, the opening being bounded by a forward facing peripheral rim;

a syringe having a hollow body, the body having a cylindrical tubular wall, a central longitudinal axis, a closed forward end having a discharge outlet therein, an open rearward end, a plunger snugly slidable within the hollow body in direct contact with the inside of the tubular wall and having a rearwardly facing drive engaging coupling thereon, and a flange monolithic with the body, extending outwardly from the hollow body and perpendicular to the longitudinal axis of the body, the flange having an annular rearwardly facing surface; and

a connector partially on the injector and partially on the syringe locking the syringe to the opening on the injector upon rearward longitudinal insertion of the rearward end of the syringe into the opening and urging the rearwardly facing surface of the flange against the peripheral rim of the opening to inhibit leakage of spilled fluid into the injector, the connector including locking structure monolithic with the body of the syringe having an outer breadth smaller than the outward extension of said flange and spaced a fixed distance rearward of the flange and mating structure on the injector within the opening spaced the fixed distance rearward of the peripheral rim of the opening.

35. The injector of claim 34 wherein the locking structure includes screw threads in the form of a plurality of circumferentially spaced thread sections extending outwardly from the tubular wall of the syringe and the mating structure includes a plurality of circumferentially spaced mating thread sections spaced around the opening on the injector.

36. The injector of claim 35 wherein:

the screw threads include thread sections each spanning less than the circumference of the body so as to enable threaded engagement with the mating threads upon 45° rotation of the syringe.

37. The injector of claim 34 wherein:

the flange is in the form of a continuous annular ring surrounding the tubular body at the forward end thereof, and the connector includes locking structure extending radially from the tubular wall and spaced rearwardly from the ring, urging the ring against the peripheral rim of the opening so as to form a seal therewith to inhibit leakage of spilled fluid from entering the injector.

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UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. : 5,658,261

DATED : August 19, 1997

INVENTOR(S) : Neer et al.

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Column 4, Line 22, after the word "plunger", replace "cut" with --out--.

Column 10, Line 30, after the word "jaws", insert the number --114--.

Column 13, line 2, delete the word "form", replace it with --from--.

Column 13, line 25, after the word "positioned", insert the word --on--.

Column 14, line 29, Claim 2, delete the word "internal", first occurrence.

Column 17, line 27, Claim 22, after the word "injector", insert --of--.

Column 17, line 34, Claim 23, after the word "injector", insert --of--.

Signed and Sealed this

Twenty-fourth Day of March, 1998

Attest:

BRUCE LEHMAN

Attesting Officer

Commissioner of Patents and Trademarks

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United States Patent [19]

Niehoff

[11] Patent Number: 5,662,612

[45] Date of Patent: Sep. 2, 1997

[54] **CONTROLLING PLUNGER DRIVES FOR FLUID INJECTIONS IN ANIMALS**

[75] Inventor: **Kenneth J. Niehoff**, Cincinnati, Ohio

[73] Assignee: **Liebel Flarsheim Company**, Cincinnati, Ohio

[21] Appl. No.: **494,795**

[22] Filed: **Jun. 26, 1995**

Related U.S. Application Data

[63] Continuation of Ser. No. 157,823, Nov. 24, 1993, abandoned.

[51] **Int. Cl.**^{6} **A61M 37/00**

[52] **U.S. Cl.** **604/155**; 604/151; 417/15; 417/63

[58] **Field of Search** ..... 604/67, 131, 151, 604/154, 155; 417/15, 33, 42, 43, 44 J, 63

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Brochure for "PercuPump 1A" of E–Z–EM, Inc., 717 Main St., Westbury, NY 11590, copyright 1990.

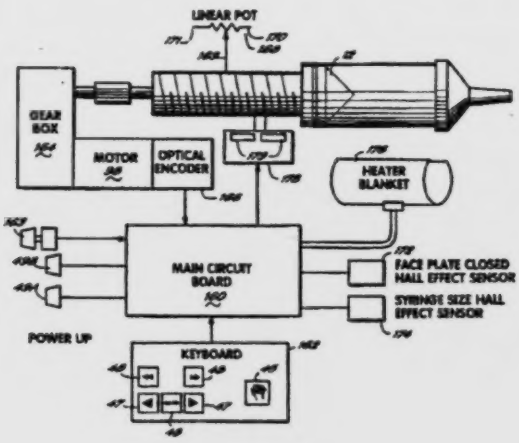
Primary Examiner—Todd E. Manahan

Attorney, Agent, or Firm—Wood, Herron & Evans, L.L.P.

[57] **ABSTRACT**

A computer-controlled injector of the type as a motor which advances and retracts a plunger located within a syringe housing toward and away from a nozzle located in the front of the syringe to inject fluid into or out of an animal subject. The injector tracks the plunger position during an injection, and compensates for plunger extenders found in partially pre-filled syringes by applying a stored offset value to the computed plunger position, to produce a corrected plunger position reflecting the actual position of the plunger and compensating for the presence of the extender. The offset value can be determined by querying the operator as to the capacity of the syringe and determining therefrom the appropriate offset value, or may be automatically computed by detecting physical indicia on the syringe or extender which indicate the length of the extender.

12 Claims, 11 Drawing Sheets



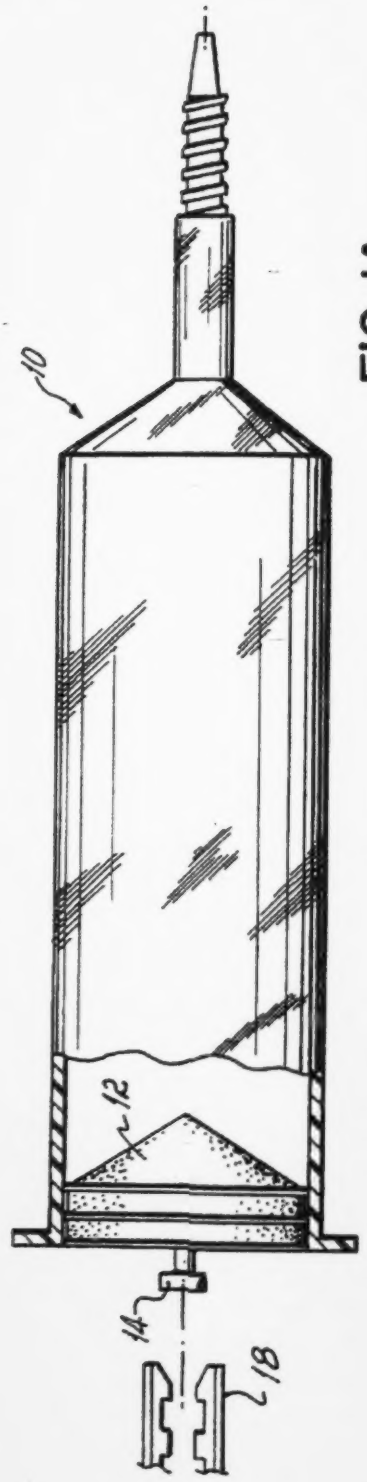


FIG. IA

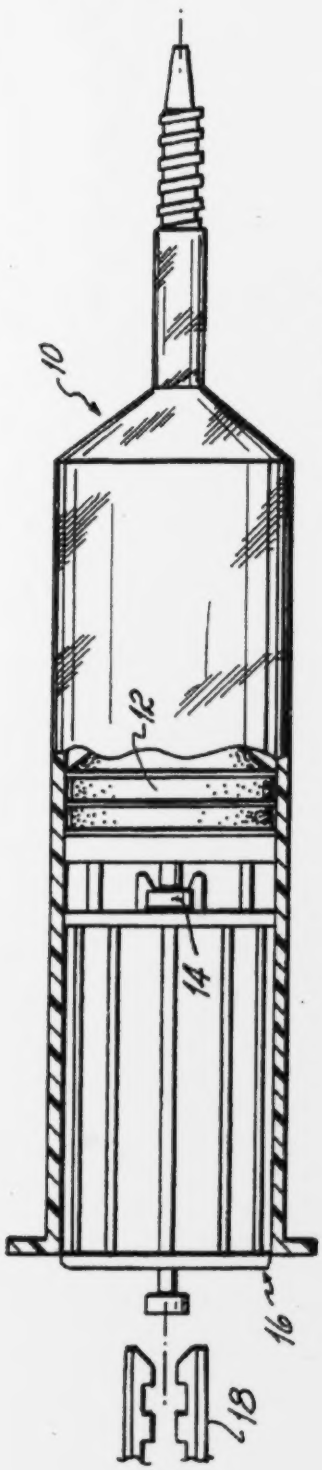


FIG.IB

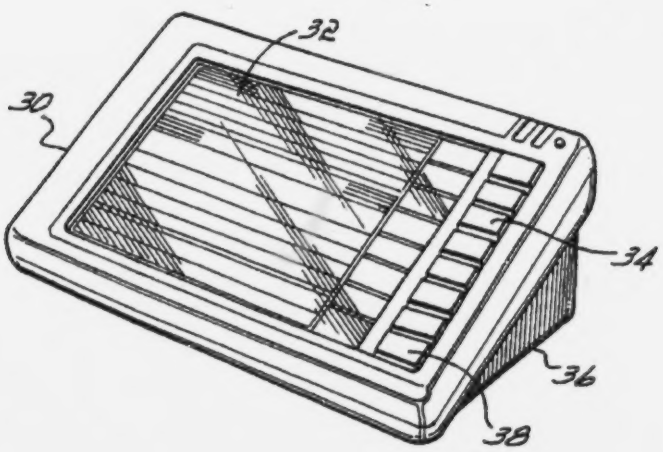


FIG. 2A

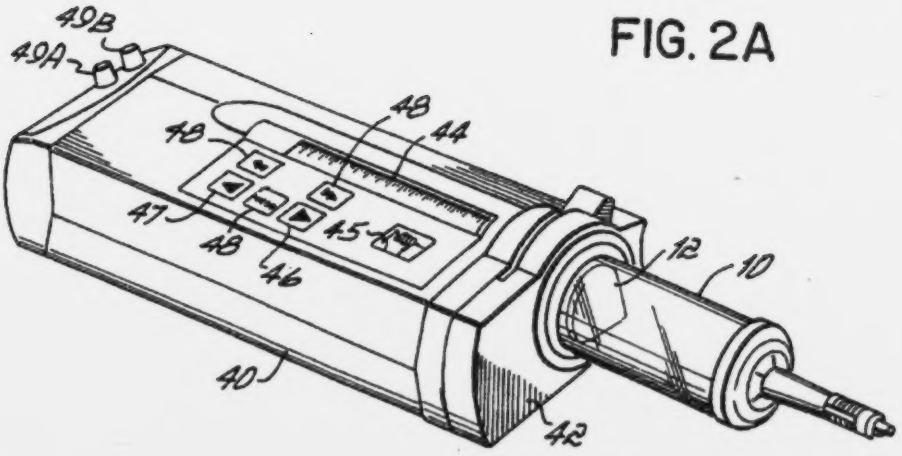


FIG. 2B

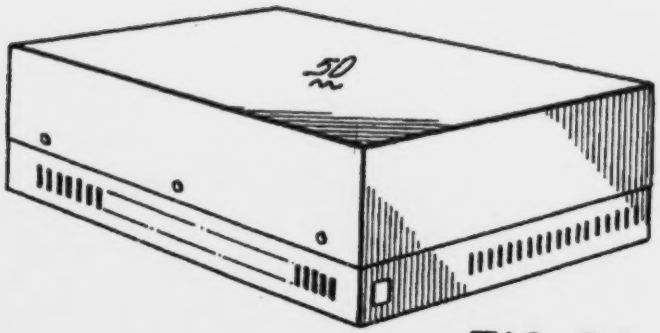


FIG. 2C

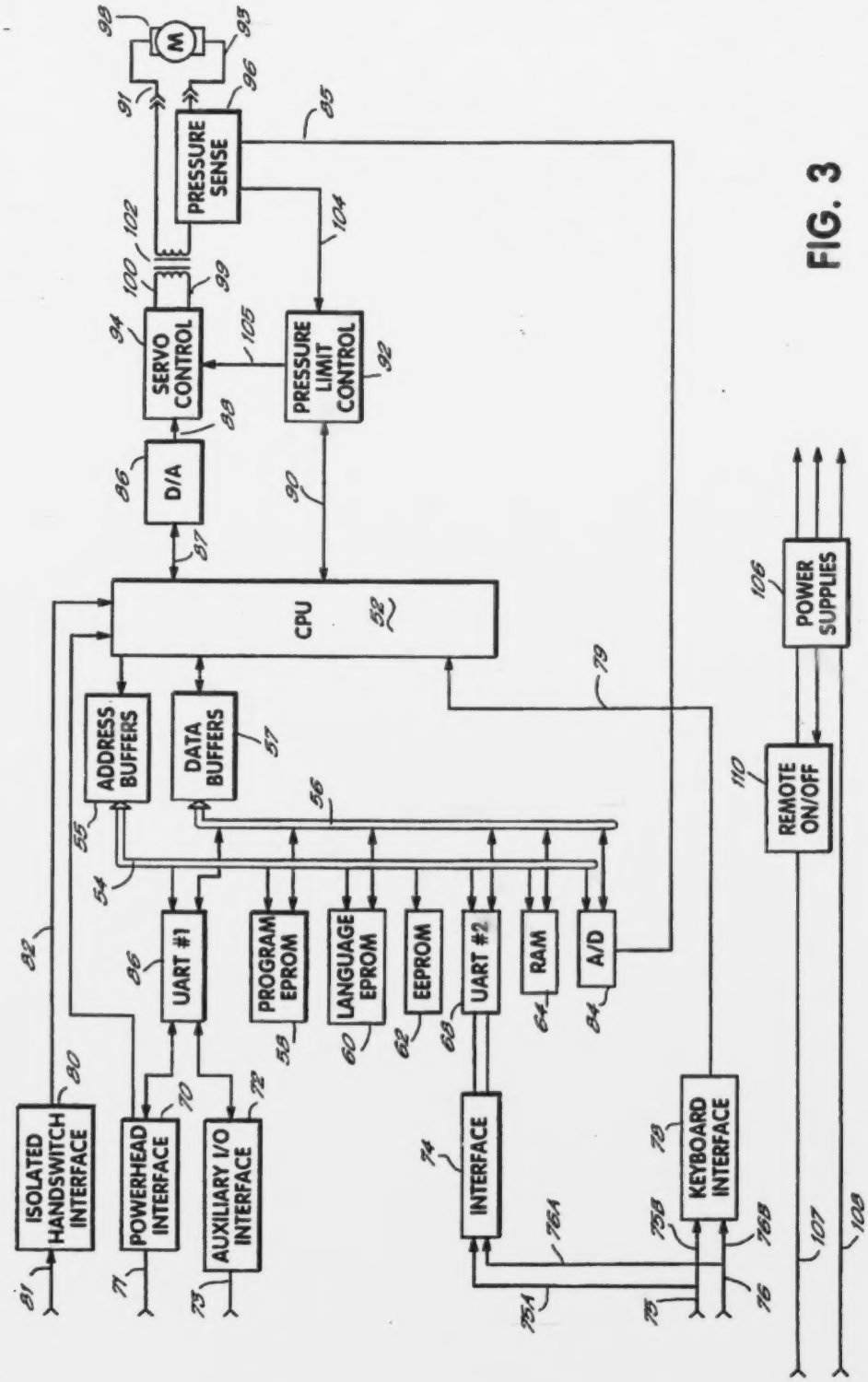

M
PRESSURE SENSE
SERVO CONTROL
PRESSURE LIMIT CONTROL
D/A
CPU
ADDRESS BUFFERS
DATA BUFFERS
UART #1
PROGRAM EPROM
LANGUAGE EPROM
EEPROM
UART #2
RAM
A/D
ISOLATED HANDSWITCH INTERFACE
POWERHEAD INTERFACE
AUXILIARY I/O INTERFACE
INTERFACE
KEYBOARD INTERFACE
POWER SUPPLIES
REMOTE ON/OFF

FIG. 3

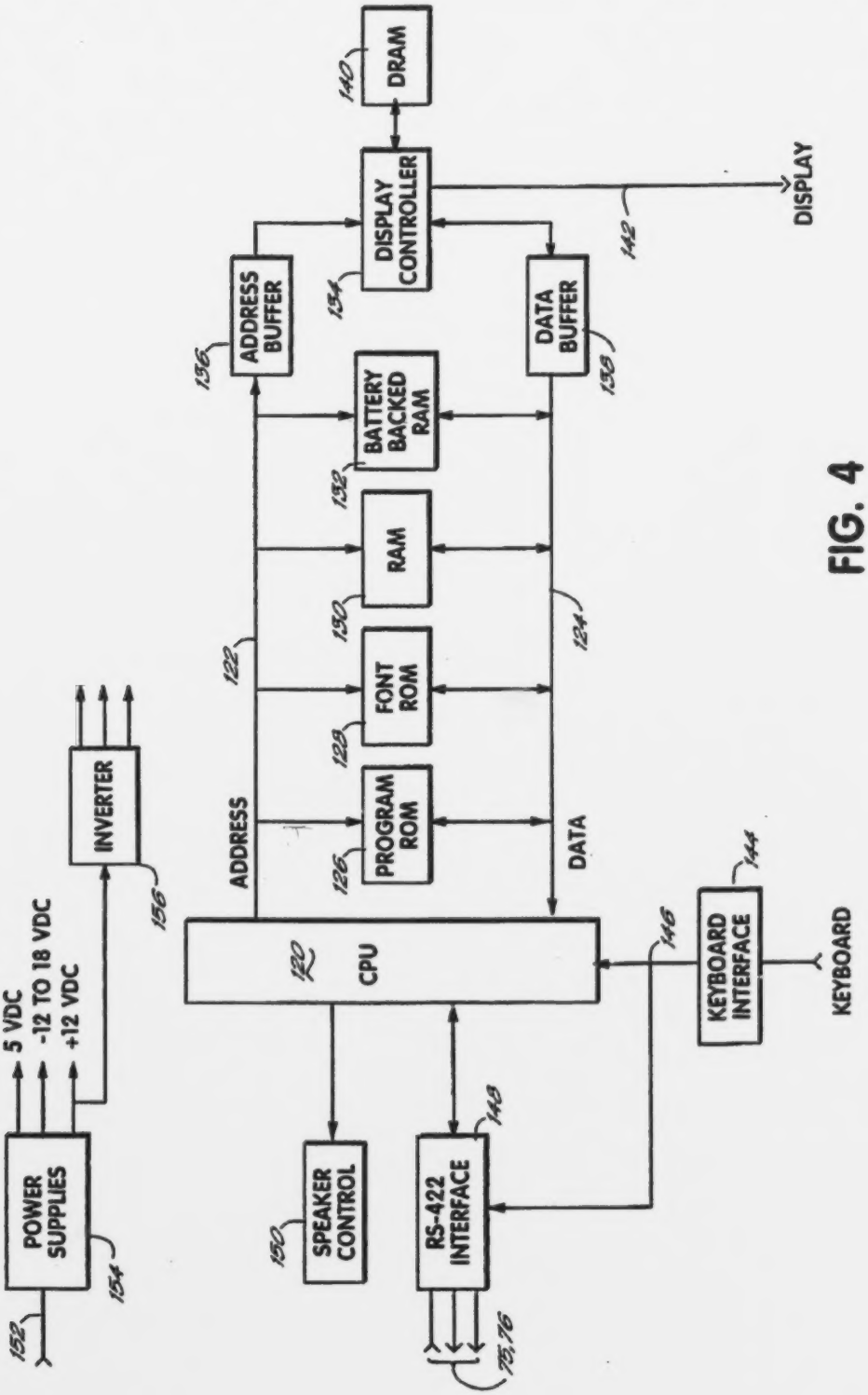

DRAM
140
DISPLAY CONTROLLER
154
DISPLAY
142
ADDRESS BUFFER
156
DATA BUFFER
158
BATTERY BACKED RAM
132
RAM
130
FONT ROM
128
PROGRAM ROM
126
ADDRESS
122
DATA
124
CPU
120
INVERTER
156
5 VDC
-12 TO 18 VDC
+12 VDC
POWER SUPPLIES
154
152
SPEAKER CONTROL
150
RS-422 INTERFACE
148
75,76
KEYBOARD INTERFACE
146
144
KEYBOARD

FIG. 4

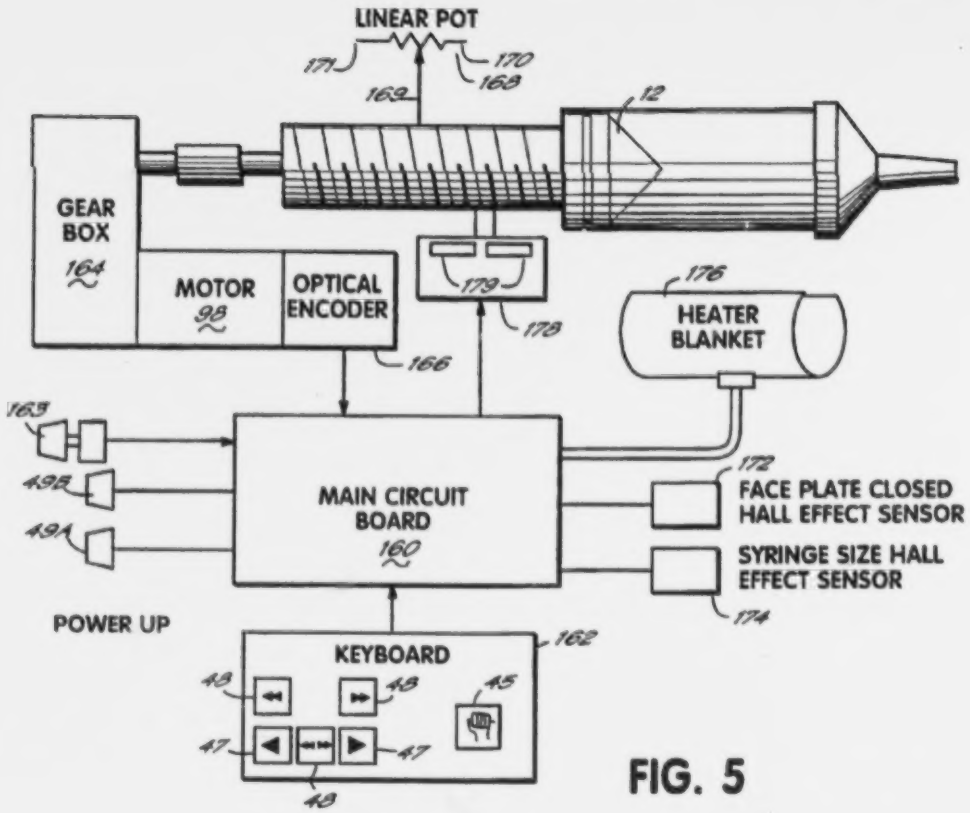

LINEAR POT
171
170
169
162
12
GEAR BOX
164
MOTOR
98
OPTICAL ENCODER
179
178
176
HEATER BLANKET
166
163
49B
49A
MAIN CIRCUIT BOARD
160
172
FACE PLATE CLOSED HALL EFFECT SENSOR
SYRINGE SIZE HALL EFFECT SENSOR
174
POWER UP
KEYBOARD
162
49
45
47
43

FIG. 5

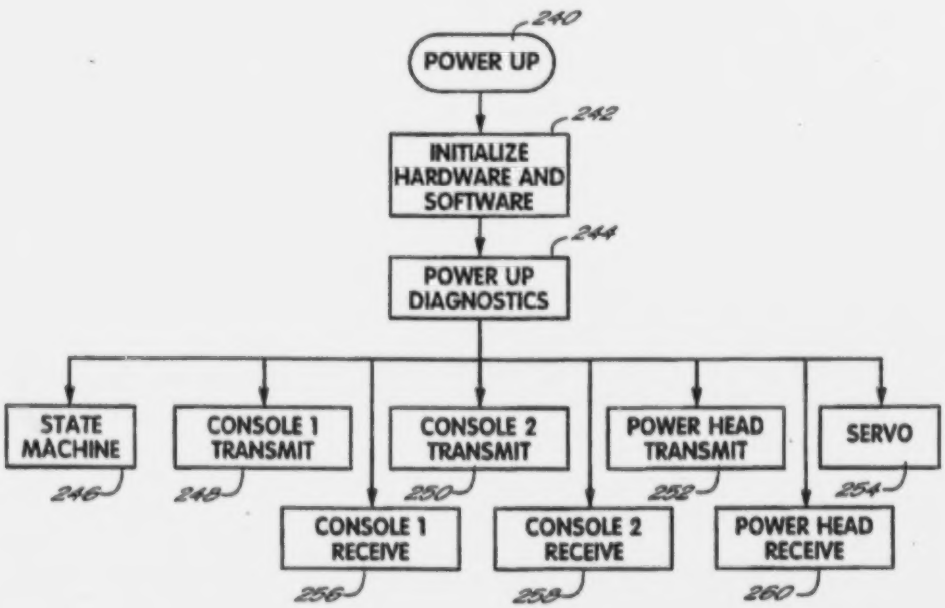

240
POWER UP
242
INITIALIZE HARDWARE AND SOFTWARE
244
POWER UP DIAGNOSTICS
STATE MACHINE
246
CONSOLE 1 TRANSMIT
248
CONSOLE 2 TRANSMIT
250
POWER HEAD TRANSMIT
252
SERVO
254
CONSOLE 1 RECEIVE
256
CONSOLE 2 RECEIVE
258
POWER HEAD RECEIVE
260

FIG.7A

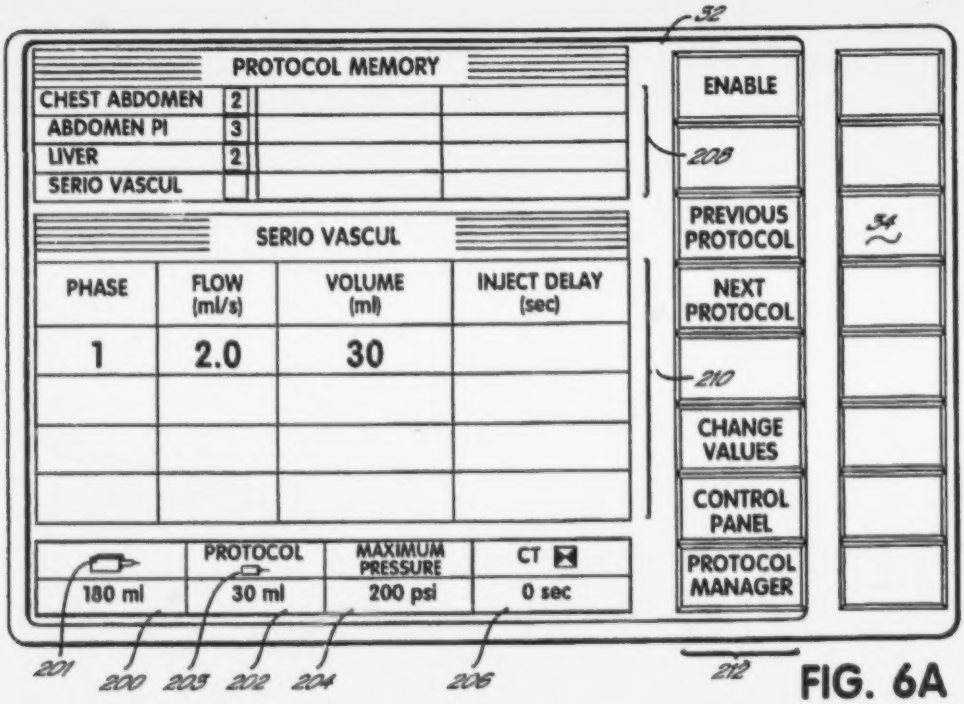

32
PROTOCOL MEMORY
CHEST ABDOMEN 2
ABDOMEN PI 3
LIVER 2
SERIO VASCUL
SERIO VASCUL
PHASE
FLOW (ml/s)
VOLUME (ml)
INJECT DELAY (sec)
1
2.0
30
PROTOCOL
MAXIMUM PRESSURE
CT
180 ml
30 ml
200 psi
0 sec
ENABLE
208
PREVIOUS PROTOCOL
NEXT PROTOCOL
210
CHANGE VALUES
CONTROL PANEL
PROTOCOL MANAGER
34
201
200
203
202
204
206
212

FIG. 6A

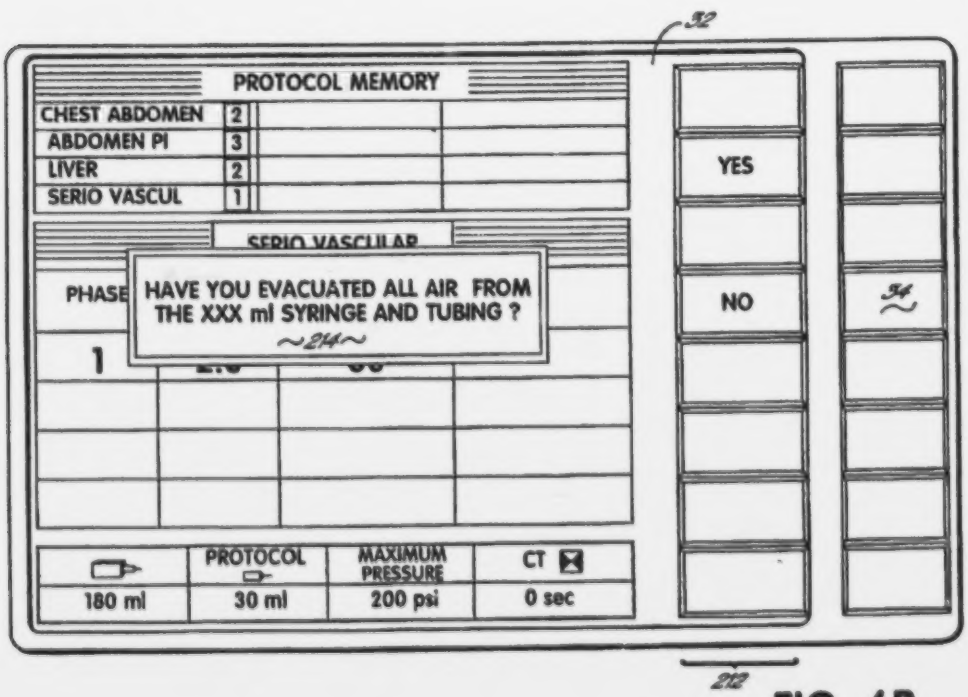

32
PROTOCOL MEMORY
CHEST ABDOMEN 2
ABDOMEN PI 3
LIVER 2
SERIO VASCUL 1
HAVE YOU EVACUATED ALL AIR FROM THE XXX ml SYRINGE AND TUBING ?
214
PHASE
1
PROTOCOL
MAXIMUM PRESSURE
CT
180 ml
30 ml
200 psi
0 sec
YES
NO
34
212

FIG. 6B

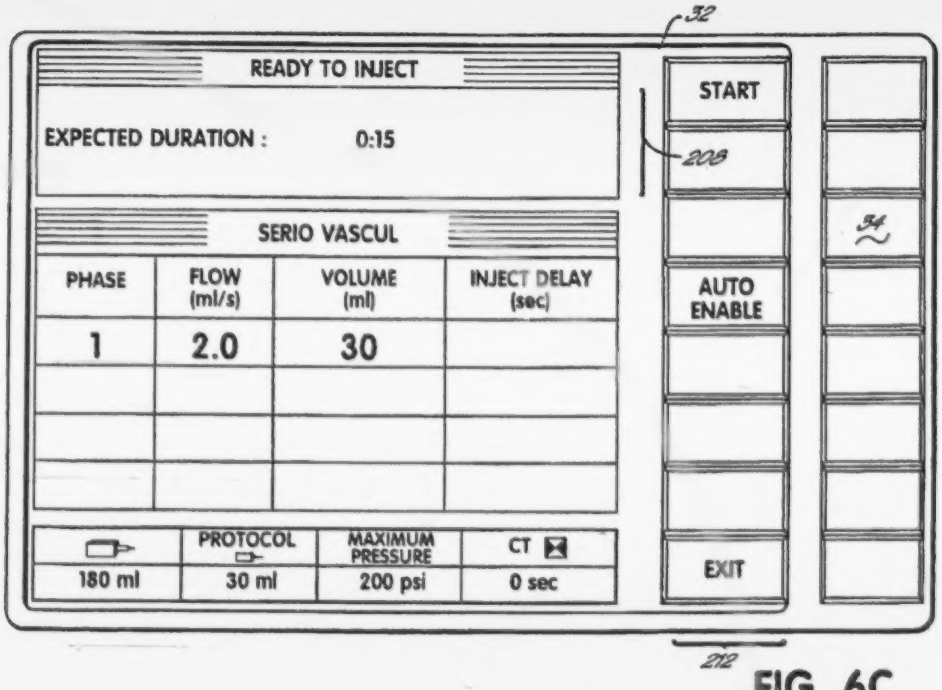

32
READY TO INJECT
EXPECTED DURATION : 0:15
SERIO VASCUL
PHASE
FLOW (ml/s)
VOLUME (ml)
INJECT DELAY (sec)
1
2.0
30
PROTOCOL
MAXIMUM PRESSURE
CT
180 ml
30 ml
200 psi
0 sec
START
208
AUTO ENABLE
EXIT
34
212

FIG. 6C

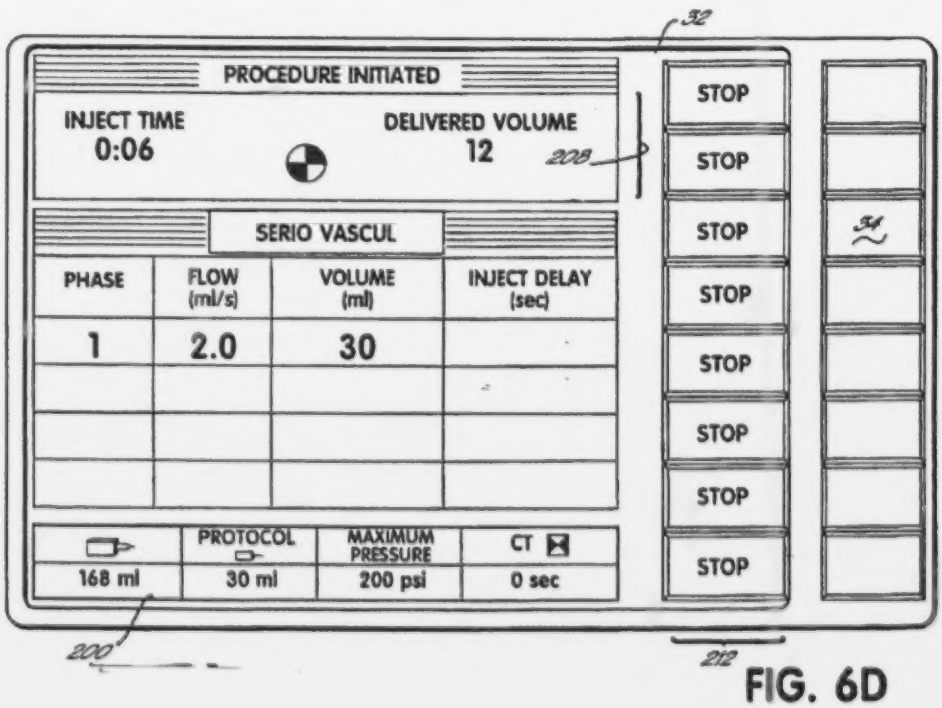

32
PROCEDURE INITIATED
INJECT TIME
0:06
DELIVERED VOLUME
12
208
SERIO VASCUL
PHASE
FLOW (ml/s)
VOLUME (ml)
INJECT DELAY (sec)
1
2.0
30
PROTOCOL
MAXIMUM PRESSURE
CT
168 ml
30 ml
200 psi
0 sec
STOP
STOP
STOP
STOP
STOP
STOP
STOP
STOP
34
200
212

FIG. 6D

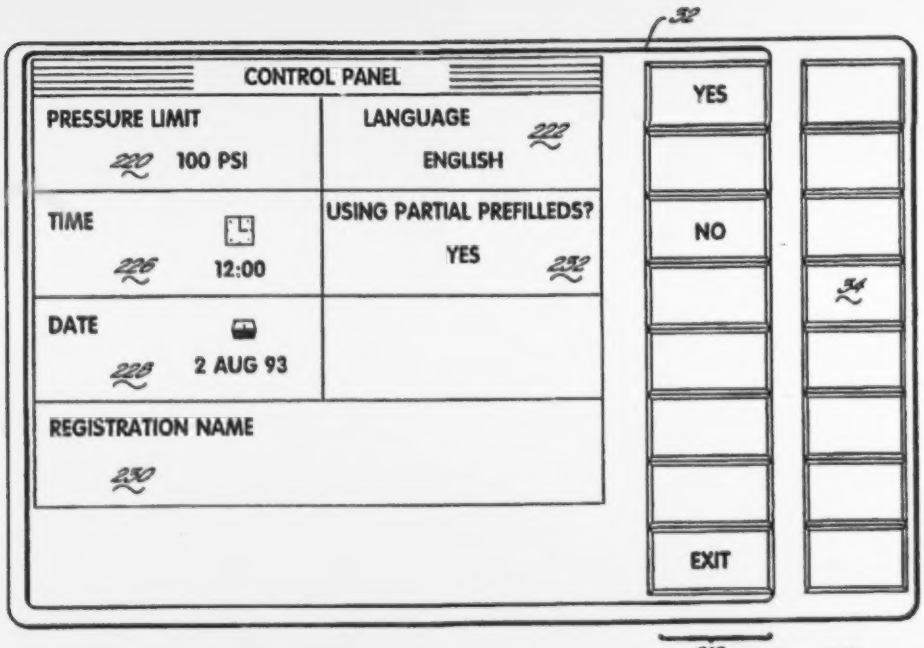

32
CONTROL PANEL
PRESSURE LIMIT
220
100 PSI
LANGUAGE
222
ENGLISH
TIME
226
12:00
USING PARTIAL PREFILLEDS?
YES
232
DATE
228
2 AUG 93
REGISTRATION NAME
230
YES
NO
EXIT
34
212

FIG. 6E

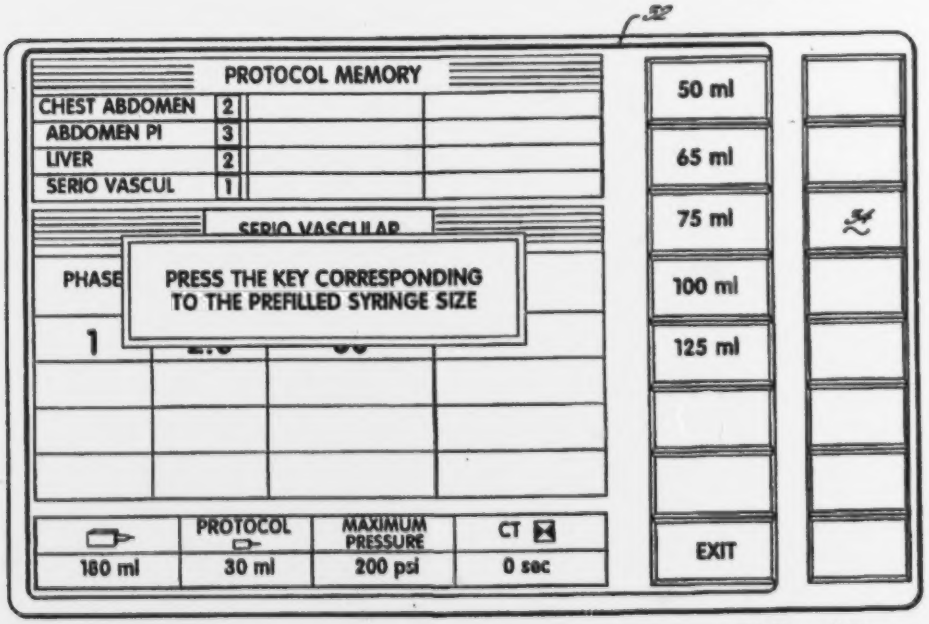

32
PROTOCOL MEMORY
CHEST ABDOMEN 2
ABDOMEN PI 3
LIVER 2
SERIO VASCUL 1
SERIO VASCULAR
PHASE
PRESS THE KEY CORRESPONDING TO THE PREFILLED SYRINGE SIZE
1
PROTOCOL
MAXIMUM PRESSURE
CT
180 ml
30 ml
200 psi
0 sec
50 ml
65 ml
75 ml
100 ml
125 ml
EXIT
34

FIG. 6F

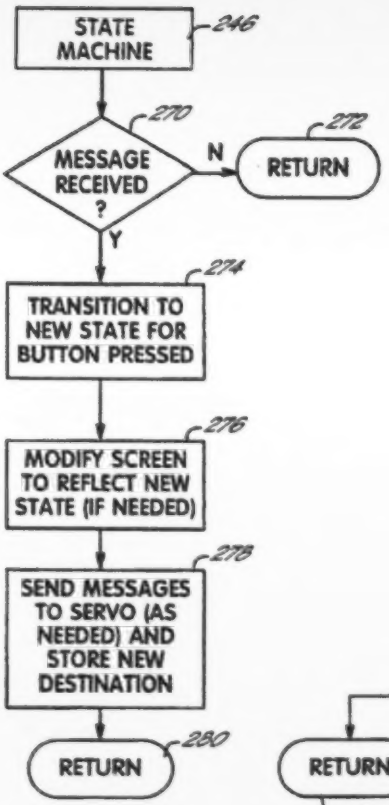

STATE MACHINE
246
270
MESSAGE RECEIVED ?
N
272
RETURN
Y
274
TRANSITION TO NEW STATE FOR BUTTON PRESSED
276
MODIFY SCREEN TO REFLECT NEW STATE (IF NEEDED)
278
SEND MESSAGES TO SERVO (AS NEEDED) AND STORE NEW DESTINATION
RETURN
280

FIG.7B

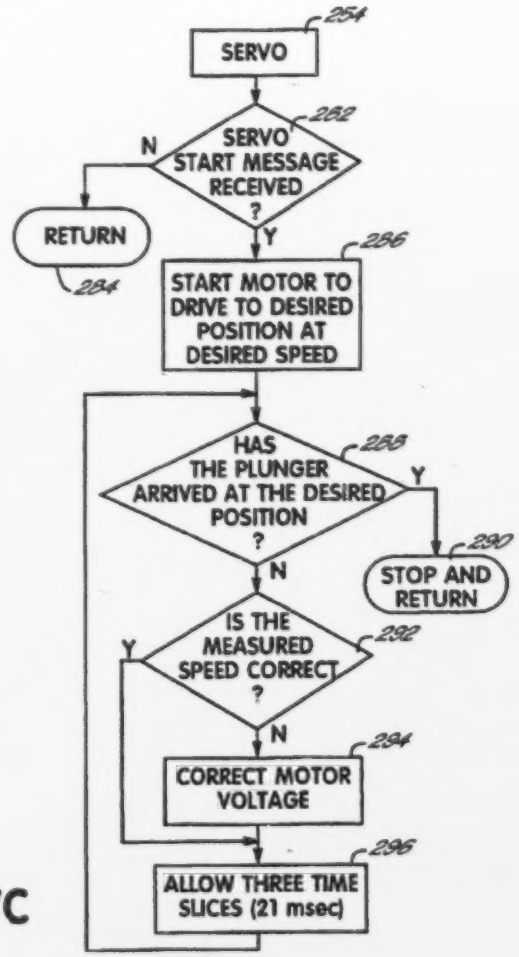

SERVO
254
282
SERVO START MESSAGE RECEIVED ?
N
RETURN
284
Y
286
START MOTOR TO DRIVE TO DESIRED POSITION AT DESIRED SPEED
288
HAS THE PLUNGER ARRIVED AT THE DESIRED POSITION ?
Y
290
STOP AND RETURN
N
292
IS THE MEASURED SPEED CORRECT ?
Y
N
294
CORRECT MOTOR VOLTAGE
296
ALLOW THREE TIME SLICES (21 msec)

FIG.7C

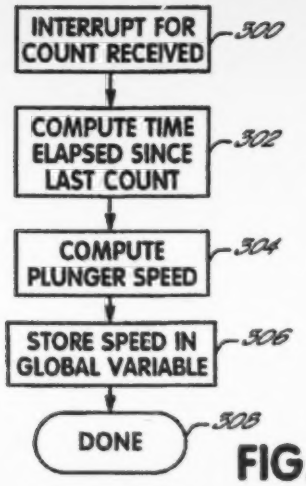

INTERRUPT FOR COUNT RECEIVED
300
COMPUTE TIME ELAPSED SINCE LAST COUNT
302
COMPUTE PLUNGER SPEED
304
STORE SPEED IN GLOBAL VARIABLE
306
DONE
308

FIG.7D

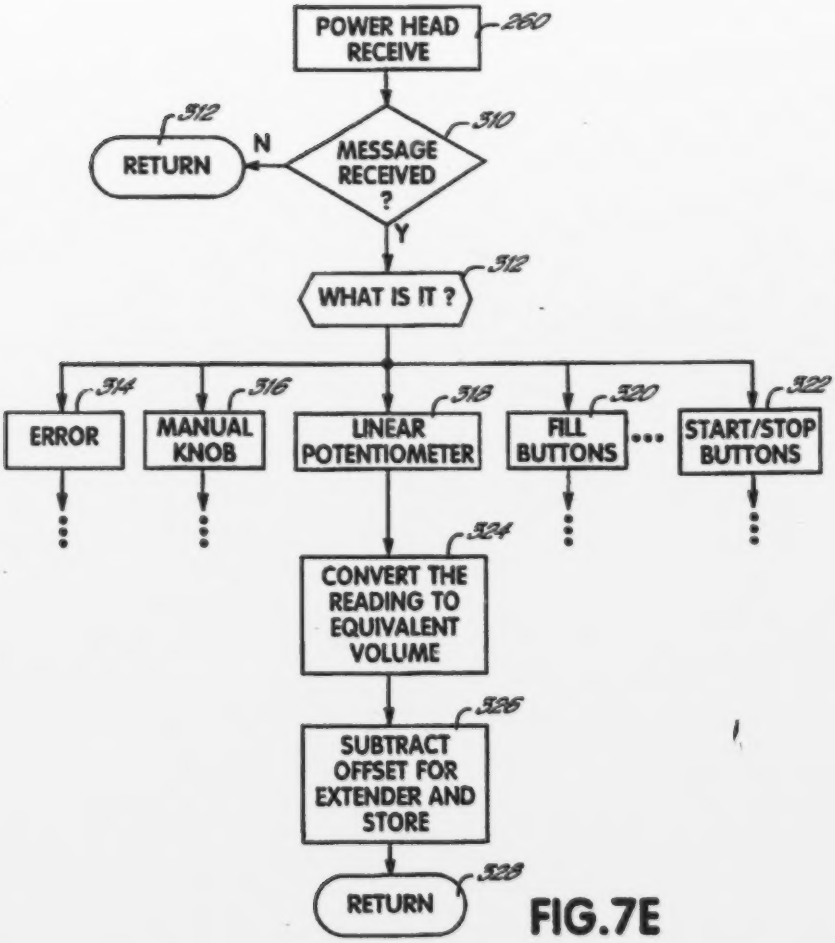

POWER HEAD RECEIVE
260
MESSAGE RECEIVED ?
310
N
RETURN
312
Y
WHAT IS IT ?
312
ERROR
314
MANUAL KNOB
316
LINEAR POTENTIOMETER
318
FILL BUTTONS
320
START/STOP BUTTONS
322
CONVERT THE READING TO EQUIVALENT VOLUME
324
SUBTRACT OFFSET FOR EXTENDER AND STORE
326
RETURN
328

FIG.7E

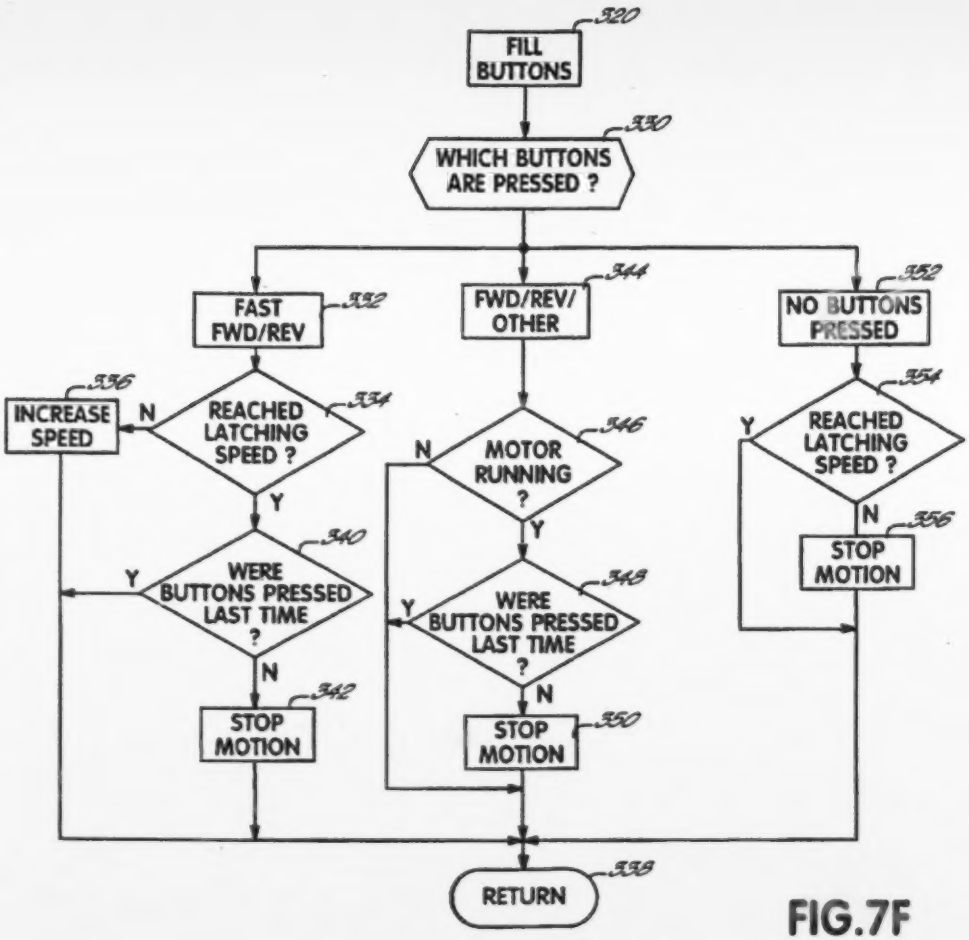

320
FILL BUTTONS
330
WHICH BUTTONS ARE PRESSED ?
FAST FWD/REV
332
FWD/REV/ OTHER
344
NO BUTTONS PRESSED
352
INCREASE SPEED
336
N
REACHED LATCHING SPEED ?
334
Y
346
MOTOR RUNNING ?
N
Y
354
REACHED LATCHING SPEED ?
Y
N
356
STOP MOTION
340
Y
WERE BUTTONS PRESSED LAST TIME ?
N
348
Y
WERE BUTTONS PRESSED LAST TIME ?
N
342
STOP MOTION
350
STOP MOTION
338
RETURN

FIG.7F

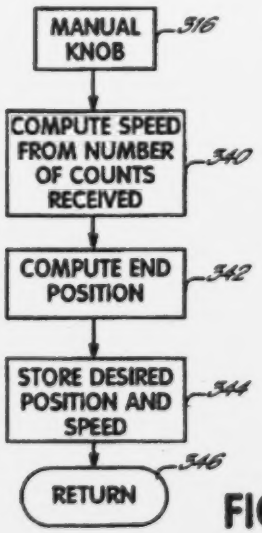

MANUAL KNOB
316
COMPUTE SPEED FROM NUMBER OF COUNTS RECEIVED
340
COMPUTE END POSITION
342
STORE DESIRED POSITION AND SPEED
344
RETURN
346

FIG.7G

CONTROLLING PLUNGER DRIVES FOR FLUID INJECTIONS IN ANIMALS

RELATED APPLICATION

This application is a continuation of application Ser. No. 08/157,823 filed Nov. 24, 1993 entitled CONTROLLING PLUNGER DRIVES FOR FLUID INJECTIONS IN ANIMALS, now abandoned.

CROSS REFERENCE TO RELATED APPLICATIONS

This application is related to previously-filed U.S. patent application Ser. No. 07/881,782 now U.S. Pat. No. 5,279,569 of Charles S. Neer et al., filed May 11, 1992 for METHOD AND APPARATUS FOR INJECTING FLUID INTO ANIMALS AND DISPOSABLE FRONT LOADABLE SYRINGE THEREFOR, which is assigned to the same entity as this application.

REFERENCE TO MICROFICHE APPENDIX

A microfiche appendix is attached to this application. The software in this appendix is subject to copyright protection. The copyright owner has no objection to reproduction of the appendix in the form that it appears in the U.S. Patent and Trademark Office, but reserves all other rights under copyright law.

BACKGROUND OF THE INVENTION

Injectors are devices that expel fluid, such as radiopaque media (contrast fluid) used to enhance x-ray or magnetic images, from a syringe, through a tube, and into an animal subject. Injectors are typically provided with an injector unit, adjustably fixed to a stand or support, having a plunger drive that couples to the plunger of the syringe and may move the plunger forward to expel fluid into the tube, or move the plunger rearward to draw fluid into the syringe to fill it.

Injectors often include control circuits for controlling the plunger drive so as to control the rate of injection and amount of fluid injected into the subject. Typically, the control circuit includes one or more manual switches which allow a user to manually actuate the plunger drive to move the plunger into or out of the syringe; typically the user holds down a "forward" or "reverse" drive switch to move the plunger in the indicated direction.

To reduce the risk of infection, in a typical injection procedure the syringe is only used once, and is disposed after use. In some cases, the syringe is inserted into the injector empty. The empty syringe is filled by retraction of the plunger while the interior of the syringe communicates with a supply of the contrast fluid via an injection tube connected between the nozzle of the syringe and the supply of media. Then, bubbles are removed from the syringe, and the injection is performed. At the end of the procedure, the syringe plunger typically is forward, as is the plunger drive.

In some injectors, the syringe can only be removed or replaced while the plunger drive is fully retracted. As illustrated in FIG. 1A, typically an empty syringe **10** is filled with sterile air, with the plunger **12** at the fully retracted position as shown. The plunger drive includes a jaw **18** designed to engage and disengage a button **14** on the rear side of the plunger while the plunger is in this fully-retracted position. Before an empty new syringe can be filled, it is necessary that the plunger be moved fully forward in the syringe so that the syringe can be filled by rearward retraction of the plunger. Thus, the reloading operation can involve fully retracting the plunger drive to allow removal and replacement of the syringe, then fully advancing the plunger drive and plunger to expel air from the syringe, and then retracting the plunger drive and plunger to fill the syringe. These lengthy, manual movements of the plunger and drive are time consuming.

The above-referenced patent application describes a front-loading injector in which a syringe can be replaced even though the plunger drive is not fully retracted. This injector substantially reduces the number of plunger drive movements necessary to prepare a syringe for a new injection; after an injection, the syringe can be removed and replaced without moving the drive from its fully-advanced position. (The plunger drive jaw **18** can engage and disengage button **14** regardless of the position of the plunger.) After the syringe is replaced, the drive is retracted, filling the syringe for a new injection. Thus, to ready the injector for a new injection, the plunger drive is manually moved once rather than three times.

Another recent development is the use of pre-filled disposable syringes. A pre-filled syringe also reduces the number of manual plunger drive movements necessary to prepare the injector for a new injection. After an injection, the plunger drive is fully retracted, the used syringe is removed and replaced with the pre-filled syringe, and the injector is ready for a new injection. Thus, again, the plunger drive is manually moved once rather than three times.

To prevent infection, contrast media remaining in a syringe after an injection must be discarded. However, contrast media is relatively expensive. For this reason, when preparing for an injection, an empty syringe is filled with only as much media as will be needed for the next injection. For the same reason, pre-filled syringes are sold in a number of capacities, e.g. ranging from 60 to 125 milliliters, allowing the operator preparing for an injection to select a syringe containing only as much media as is needed for the injection.

A typical pre-filled syringe is illustrated in FIG. 1B. In many respects, the pre-filled syringe is identical to the empty syringe shown in FIG. 1A. The barrels **10** and plungers **12** have the same size and profile in both syringes (injectors now in use accommodate only a few FDA approved syringe sizes, e.g., a 200 milliliter size and a 125 milliliter size, so all syringes use these sizes). Furthermore, both syringes have a button **14** which is initially located at the end of the barrel **10** (thus, both syringes are compatible with injectors which are designed to grip a button at the end of the syringe). The main difference is that in the pre-filled syringe of FIG. 1B, the initial location of the plunger **12** is in the middle of the syringe (thus reducing the initial volume of the pre-filled syringe). An extender **16** is attached to button **14** of the plunger, and provides a second button **18** at the end of the syringe which can be gripped by the injector.

SUMMARY OF THE INVENTION

As noted above, at the present state of the art, preparing an injector for an injection requires at least one manual movement of the plunger drive into or out of the syringe barrel, and as many as three such movements. This operation is tedious and inefficient, not only because of the time consumed, but also because the operator must press and hold manual movement switches to produce the movement, and thus is physically tied to the injector and cannot use this time to make other preparations.

In accordance with one embodiment of the present invention, the plunger drive controller has a locked mode in

which motion, initially requested by pressing a manual movement switch, will continue whether or not the operator continues pressing the switch, until the plunger drive reaches its fully-advanced or fully-retracted position. Thus, once the controller has entered the locked mode, the operator may release the manual switch and the desired movement, either advancement or retraction, will continue while the operator makes other preparations for the next injection.

In preferred embodiments, the operator causes the controller to enter the locked mode by pressing the manual movement switch for a predetermined period of time. For safety, the manual movement switch may comprise two buttons which must be simultaneously pressed to produce movement. Movement is initiated by pressing both buttons. While both buttons are held down, the plunger drive controller increases the velocity of movement until the velocity reaches a maximum, at which time the plunger drive controller enters the locked mode. If one button is released before the controller reaches maximum velocity and enters the locked mode, the movement will continue, but at a constant velocity. If the second button is released, the movement will stop. Alternatively, if the controller has reached maximum velocity and entered the locked mode, movement will continue even if both buttons are released; however, if thereafter either button is pressed, movement stops. The controller can provide visual feedback, for example via a light which blinks during motion and lights steadily when the controller is in the locked mode. This light may itself move in synchronism with the plunger drive to provide further feedback on the speed of motion.

As noted, the plunger drive controller is typically manually controlled by means of a switch which, when depressed, causes the plunger drive to move in one of two directions. In accordance with a second aspect of the invention, manual control is improved by providing an adjustment allows the operator to adjust the rate at which the plunger drive moves or accelerates. This permits the operator to customize the operation of the plunger drive controller to enhance individual comfort.

In preferred embodiments, the manual control comprises a wheel which, when rotated, causes the plunger drive to move at a speed which is proportional to the speed of rotation. Alternatively, the manual control may be a forward switch and a reverse switch which cause the plunger drive to move in the indicated direction at a programmable velocity or acceleration.

To operate effectively, the plunger drive controller must determine the location of the plunger **12** relative to the ends of the syringe **10** so that, for example, the controller can determine the amount of contrast media remaining in the syringe. This can be done by a sensor which detects the location of the plunger drive jaw **20**, which is coupled directly to and moves with the plunger **12**. However, a pre-filled syringe may include an extender **16** which changes the relative location of the plunger **12** and the plunger drive jaw **20**, leading to malfunction in the plunger drive controller. In accordance with a third aspect of the invention, malfunction is avoided by storing an offset value representative of the length of the extender **16**, and applying this offset value to the computed drive jaw position.

In preferred embodiments, the offset value may be computed by querying the operator as to the capacity of the syringe and determining therefrom the appropriate offset value. The controller may be configurable so that this query is not made (for example, if the injector will not be used with pre-filled syringes, and therefore the offset value will not change). Alternatively, the offset value may be automatically computed by detecting physical indicia on the syringe or extender which indicate the length of the extender.

These and other aspects will be further illustrated in the following detailed description with reference to the attached drawings, in which:

BRIEF DESCRIPTION OF THE DRAWING

FIGS. **1A** and **1B** are side, partial cut-away views of an empty syringe and a pre-filled syringe, respectively.

FIGS. **2A**, **2B** and **2C** respectively illustrate the console, powerhead, and powerpack of an injector.

FIGS. **3**, **4**, and **5** are electrical and electrical-mechanical block diagrams of the powerpack, console and powerhead, respectively.

FIGS. **6A**, **6B**, **6C**, **6D**, **6E** and **6F** are illustrations of displays produced by the console in operation of the injector.

FIGS. **7A**, **7B**, **7C**, **7D**, **7E**, **7F** and **7G** are flow charts illustrating the software operating within the power pack.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

Referring to FIGS. **2A**, **2B** and **2C**, an injection system according to the invention includes three main components, a console **30**, a powerhead **40** and a powerpack **50**.

The console **30** comprises a liquid crystal display **32** of the type used in notebook computers (e.g., a display sold by Sharp Electronics Corp. of 5700 N.W. Pacific Rim Blvd., Camas, Wash. 98607 as part number LM64P62), coupled to an eight key keypad **34** within a housing **36**. As is further elaborated below, display screens presented on display **32** provide injection information and present the user with menus of one or more possible operations, each operation associated with one of the keys on keypad **34**.

The powerhead **40** includes a mount **42** (such as that described in the above-referenced patent application) which accepts a syringe **10** for an injection. The powerhead includes a plunger drive motor (not shown) for moving plunger **12** forward into and rearward out of syringe **10** during an injection in accordance with a preprogrammed sequence, or protocol, selected by the operator by operation of the console **30**.

The location and movement of the plunger drive is indicated by a light emitting diode (LED) which is mounted to the plunger drive and is visible to the operator through a graduated window **44** in the side of the powerhead **40**. As noted below, this LED flashes when the plunger drive is moving, and lights steadily when the plunger drive has been manually locked into forward or reverse motion in the manner described below.

The side of the powerhead **40** includes six pushbuttons: a start/stop button **45**, a forward manual motion button **46**, a reverse manual motion button **47**, and an enable/accelerate button **48**. The three enable/accelerate buttons **48** perform the same function; there are three buttons instead of one to improve operator accessibility.

The start/stop button **45** is used to start an injection protocol selected at the console, or to stop and restart an injection. During an injection, all of the eight buttons on the keypad **34** of the console **30** will perform an identical start and stop function. Furthermore, a remote handswitch (not shown) may be connected to the powerpack **50** (see below) to perform a start and stop function. (For this reason, the start/stop button **45** includes a picture of a handswitch.)

To manually move the plunger drive, the operator must simultaneously press a motion button **46** or **47** and an enable button **48**. This is a safety feature which reduces the risk of accidental movement of the plunger. If the operator presses the forward button **46** and any of the three enable buttons **48**, the plunger will begin forward motion; conversely, if the operator presses the reverse button **47** and any of the three enable buttons **48**, the plunger will begin reverse motion. Once motion is initiated in either direction, the operator may release one of the buttons; motion will be maintained at a constant velocity in the same direction so long as any one of the five buttons **46**, **47** or **48** is held down. If, instead, after initiating motion in one direction, the operator continues to hold down an enable button **48** and a motion button **46** or **47**, motion will not only be maintained in the same direction, but will be accelerated in this direction until either the operator releases one of the buttons or a maximum velocity is achieved. At any time during the acceleration, the operator may release one of the buttons and hold down the other, and the motion will continue at the same velocity without acceleration. Thereafter, the operator can re-depress the released button, at which time acceleration will begin again.

If the velocity of motion increases to a maximum value, the plunger drive controller (described in more detail below) will enter a locked mode. In this locked mode, movement will continue at the maximum velocity in the same direction even if the operator releases all of the buttons. This frees the operator to perform other tasks when preparing for an injection without being forced to hold manual buttons on the injector until the plunger drive has made the lengthy transition to its fully-advanced or fully-retracted position.

For safety reasons, the locked mode can be terminated readily. If the operator has entered the locked mode and thereafter released all of the buttons, if at any time thereafter any of the buttons is pressed, the plunger drive controller will exit the locked mode and terminate motion.

Two lights **49A** and **49B** mounted on the rear of the powerhead **40** indicate the status of operation of the injector. Light **49A** is an injecting/fault indicator. This light glows while an injection is in process. It will flash if an error is detected. Light **49B** is an enabled indicator. It glows when the injector has been enabled and is ready to perform an injection protocol.

The rear end of the powerhead **40** (opposite mount **42**) includes a jog wheel or switch (not shown in FIG. 2B, see **163**, FIG. 5) used, in the manner described below, to manually activate motion of the plunger drive.

The powerpack **50** illustrated in FIG. 2C contains electronics which communicate with the console **30** and powerhead **40** to perform the functions described above. The powerpack is connected to the console **30** and powerhead **40** by standard computer communications cables (not shown). Signals carried on these cables are interfaced to circuitry inside of the powerhead, console, and powerpack in a manner described below.

As shown in FIG. 3, the circuitry in the powerpack includes a central processing unit (CPU) **52** which controls the operations of the powerhead **40** and console **30**. The CPU is preferably a programmable microprocessor such as the MC68332FN microprocessor, manufactured by Motorola, 2110 East Elliot, Tempe, Ariz. 85284. This microprocessor is a member of the 68000 family of microprocessors and features multitasking support; it is designed for use in so called "embedded" environments such as the circuit described herein, and therefore has more than the usual number direct-wired input-output ports.

The CPU connects to an address bus **54** for addressing a number of memory and communications components and a data bus **56** for retrieving and/or sending data from and to these components. Buffers **55** and **57** aid CPU **52** in interfacing to the address and data busses, respectively. Each of the elements connected to the address and data busses are briefly described below.

An erasable programmable read-only memory (EPROM) **58** connected to data bus **56** contains the program software which operates the CPU **52**. The EPROM contains an operating system, which performs low-level management of the CPU and its communications with other circuits, and a custom program for controlling the console and powerhead to perform injection protocols. In one embodiment, the operating system software is the USX68K operating system, a multi-tasking operating system for 68000 series microprocessors sold by U.S. Software of 14215 N.W. Science Park Drive, Portland, Oreg., 97229, and the custom program is written in the "C" programming language. This custom program is described below, and a copy of the "C" language source code for the custom program appears in the appendix to this application.

A second EPROM **60** connected to data bus **56** contains language information used by the program software in EPROM **56** when generating displays for presentation on the display **32** (FIG. 2A). As will be further elaborated below, the display screens presented on the display **32** include textual descriptions of actions being taken by the injector, and menu selections which the operator can select. The textual portions of these display elements are stored in the language EPROM **56**, from which they are retrieved and inserted into a template as CPU **52** is producing a display screen. Preferably, the language EPROM contains multiple versions of each textual insert, representing different languages, so that the operator can, through menu choices entered at the console keypad **34**, choose a preferred language in which to generate screen displays. An exemplary set of languages suitable for the North American and European markets would be English, German, French and Spanish.

A third, electrically erasable and programmable read only memory (EEPROM) **62** is attached to the data bus. EEPROM **62** stores data in a non-volatile manner (so that it will not be lost when the power is turned off). Among other things, EEPROM **62** stores preprogrammed injection protocols. These protocols are created and stored by the user as desired (details are reviewed with reference to FIG. 6A, below). In addition, EEPROM **62** stores calibration information, used by CPU **52** in interpreting fluid pressure and plunger position information which it receives while performing an injection. Further, EEPROM **62** stores information on the most recently completed injection, such as the injection time and volume, so that this information may be retrieved by the operator. EEPROM **62** also stores operator preference data entered by the operator into the console (see FIG. 6E, below). This includes the preferred display language, time, and date formats. Moreover, EEPROM **62** stores operating parameters such as a programmable pressure limit, and a flag (used in the manner described below) indicating whether the injector will be used with partially pre-filled syringes of the kind illustrated in FIG. 1B. Finally, EEPROM **62** stores the registered name and/or number of the machine owner, to facilitate service and on-line customer support.

Data bus **56** is also connected to a random access memory (RAM) **64** which is used by the operating system to store a stack of register values generated during CPU operations

and machine state information corresponding to currently inactive processes running on the CPU. The application software uses the remaining Space in RAM **64** (as managed and allocated by the operating system) to store variables computed and manipulated during operation of the injector.

Most communications between CPU **52** and the powerhead **40** and console **30** flow through one of two universal asynchronous receiver/transmitters (UARTs) **66**, **68** which are connected to the data bus. A UART is a communications circuit, generally available in integrated circuit form, which collects and buffers incoming and outgoing information to enable asynchronous communications between processors or computing systems over a data link. A suitable UART is the MC68681, sold by Motorola. The first UART **66** is responsible for communications with the powerhead circuitry (see FIG. 5, below), which pass through an interface **70** and a communications cable **71** connected to the powerhead. (However, pulses from the optical encoder **166** on the powerhead (FIG. 5, below) travel directly from interface **70** along line **71** to an interrupt input on the CPU **52**.) UART **66** also handles communications with an auxiliary interface **72**, which can be coupled through a communications cable **73** to a printer to allow CPU **52** to print records of an injection. Alternatively, interface **72** (or another, similar interface) can be used to attach CPU **52** to a remote computer or other external device to allow remote monitoring and/or control of the injector.

The second UART **68** is responsible for communication with the console **30** (FIG. 2A). Two consoles **30** can be connected to the powerpack via cables **75**, **76**.

Cables **75** and **76** carry data representing keystrokes and screen activity between the powerpack **50** and console **30**. This data is encoded in a communications protocol and transmitted in accordance with the RS422 standard. The encoded data is carried via lines **75** and **76** to interface **74** which encodes and decodes transmissions for a second UART **68**. UART **68** routes keystrokes received by either console via interface **74** to CPU **52** via the data bus **56**, and further routes display information produced by CPU **52** to interface **74** for transmission to the consoles via lines **75A** and **76A**.

Cables **75** and **76** also include, on separate conductors, lines **75B** and **76B**, which carry logical signals corresponding to key **38** (FIG. 2A) of each console keyboard. As elaborated below, the software driving the console displays is written so that key **38** is the most frequently used key—depending on the screen being displayed, key **38** will function as an "Exit" key to depart the screen, an "Enter" key to accept a value or selection and depart the screen, or a "Disable" or "Cancel" key to terminate an operation. (Exemplary screens are discussed below with reference to FIGS. 6A–6F.) Because key **38** is the most frequently used key, and because key **38** is used for time-sensitive input such as a cancel command, key **38** is connected to the CPU **52** differently than the other keys. Key **38** is connected directly to the CPU **52** via an interrupt line **79**; when a keystroke is detected, a non-maskable interrupt interface (NMI) **78** (which essentially constitutes a RS422 transmitter and receiver which converts the signal on lines **75B** and **76B** to a clean logic signal on line **79**) sets an interrupt on line **79**, which is immediately detected and subsequently serviced by CPU **52**.

A similar interface is used for the remote handswitch. The cable **81** leading from the handswitch connects to the handswitch interface circuit **80** which among other things, electrically isolates the handswitch from the powerpack ground, and "de-bounces" the handswitch (eliminates electrical noise created when the switch is pressed or released) so as to provide a clean logic signal indicating whether the handswitch button is being pressed or is released. This logic signal is connected, via line **82**, to a time processor unit (TPU) port on CPU **52**. CPU **52** reads the logic signal at this TPU port and responds appropriately according to the software in EPROM **58**.

The last component on the CPU data bus **56** is an analog to digital converter (A/D) **84**. This converter is used to generate a digital signal, readable through data bus **56**, which corresponds to an analog signal received on line **85**. A suitable A/D converter is the LT1094, sold by Linear Technology of 1630 McCarthy Blvd., Milpitas, Calif. 95035. A/D converter **84** is used by the motor servo control circuitry described below. The CPU has two additional interfaces to the motor servo control circuitry: an interface on line **87** to a digital to analog converter (D/A) **86** (which generates an analog signal on line **88** corresponding to a digital signal received on line **87**, for example the AD7245, sold by Analog Devices of One Technology Way, P.O. Box 9106, Norwood, Mass. 02062), and a second interface on line **90** to pressure limit control circuit **92**. These interfaces (lines **87** and **90**) connect to synchronous peripheral interface (SPI) channels on the microprocessor, and are controlled in accordance with the software in EPROM **58**.

The D/A **86**, A/D **84**, servo control **94**, pressure limit control **92**, and pressure sense **96** circuits collectively form a motor servo control circuit which controls the operation of the motor **98** which drives the syringe plunger into and out of the syringe. (Motor **98** is shown for clarity, but it should be understood that motor **98** is physically located in the powerhead **40** (FIG. 2B, 5); lines **91** and **93** connect to the motor through several conductors of the computer interface cable connecting the powerhead **40** and the powerpack.)

Servo control circuit **94** responds to an analog voltage produced by D/A **86** on line **88** and produces a corresponding voltage between lines **99** and **100**. The voltage on lines **99** and **100** is transformed by transformer **102** to a level sufficient to drive motor **98** via lines **91** and **93**. Servo control circuit **94** contains a flyback transformer circuit which produces an output voltage related to the duty cycle of a switching FET. This duty cycle is produced by a UC3525 pulse width modulation (PWM) circuit—an integrated circuit which produces a 100 kHz digital output signal having a duty cycle which varies from 0% to 50% in response to an analog input voltage on line **88**. A suitable PWM circuit is the UC3525, sold by Unitrode of 7 Continental Boulevard, Merrimack, N.H. 03054. Thus, CPU **52** controls the speed and power output of motor **98** by writing a digital word representing a desired output voltage to D/A **86** via lines **87**; this digital word is then converted to an analog signal, and the analog signal is converted to a pulse width modulated control signal in the servo control, resulting in the desired output voltage at the motor.

Pressure sense circuit **96** includes a current sense circuit of which detects the current flow through line **93** (i.e., through the motor) and produces analog signals on lines **104** and **85** proportional to the detected current. In essence, this current sense circuit comprises a low-value, high power rating resistor in series with line **93** which attached to the motor **98**. A differential voltage amplifier (based on a low-noise, high common mode rejection op-amp) senses the voltage across the resistor and converts it to an analog voltage on lines **85** and **104**. The current flow through the motor is proportional to the force exerted by the motor and therefore to the injection pressure. Thus, the analog signals

produced by pressure sense circuit **96** can be used to derive the injection pressure.

Pressure limit control circuit **92** uses the analog signal on line **104** to perform a hardware pressure control function. Pressure limit control circuit **92** contains a commercially available digital potentiometer, used to produce an analog comparison voltage. A suitable potentiometer is the DS1267, sold by Dallas Semiconductor of 4350 Beltwood Parkway South, Dallas, Tex. 75244. CPU **52** (via lines **90**) programs this potentiometer to produce a comparison voltage corresponding to the maximum allowable pressure. Pressure limit control circuit **92** includes a comparator which compares the analog signal on line **104** produced by pressure sense circuit **96** to the comparison voltage. If the pressure exceeds the maximum allowable pressure (indicating a failure in the CPU **52**), a digital signal is transmitted on line **105** to servo control circuit **94**, which in response ignores the analog signal on line **88**, and instead reduces the voltage on lines **99** and **100** to halt the motor. Thus, once the CPU **52** has programmed pressure limit control circuit **92** with the correct maximum pressure, the injector will not exceed this pressure even if the CPU **52** fails.

Under normal conditions, this hardware pressure limit will not be activated, because CPU **52** continuously obtains feedback on the performance of the motor and the pressure produced and controls the motor through D/A **86** to achieve the desired injection protocol. CPU **52** obtains feedback on an ongoing injection from three sources: (1) feedback on the injection pressure is obtained from A/D **84**, which produces a digital word on bus **56** corresponding to the analog voltage on line **85** produced by pressure sense circuit **96**; (2) feedback on the motor speed is obtained from an optical encoder **166** physically coupled to the motor inside of the powerhead **40** (elaborated with reference to FIG. **5**, below); and (3) feedback on the position of the plunger inside of the syringe is obtained from a linear potentiometer **168** physically coupled to the plunger (see FIG. **5**, below). Using this information, CPU **52** carefully controls the injection pressure, volume and speed according to a pre-programmed protocol under control of software in EPROM **58**.

Power for the powerpack, powerhead, and console display is supplied by the AC power lines **107** and **108**. The AC line voltage is conditioned by a conventional power supply circuit **106** which includes a transformer which can be adjusted for use with non-United States line voltages, and a voltage sense circuit for selecting the appropriate transformer based on the detected line voltage. The power may be turned off by unplugging the injector, or preferably by a toggle switch which opens and closes a solid-state relay in remote on/off circuit **110**.

Referring to FIG. **4**, the console circuitry is also built around a general purpose CPU **120**. A suitable microprocessor is the MC68332FN. The address bus **122** and data bus **124** connected to CPU **120** connect to a number of supporting circuits. Program ROM **126** contains the software which directs CPU **120**. (This software is written in assembly language, and is included in the attached appendix). Font ROM **128** includes font information retrieved by CPU **120** in producing fonts for text generated on the display screen. These fonts include foreign-language characters where necessary to support foreign language text. RAM **130** is used by microprocessor in performing display and retrieval operations. Battery-backed RAM **132** stores the current time of day, so that the powerpack may make a date and time-stamped record of an injection.

The primary function of the console circuitry is to generate screens on the display **32**, and to receive keystrokes from the eight-key keypad **34** (FIG. **2A**) and relay the keystrokes to the powerpack. Displays are generated by a display controller **134**, such as the F82C455 VGA controller sold by Chips & Technologies of 3050 Zanker Road, San Jose, Calif. 95134. This VGA controller interacts with CPU **120** via an address buffer **136** and data buffer **138**, and stores screen information in a dynamic random access memory (DRAM) **140**. Information is sent over lines **142** to the display **32**.

Keystrokes from the keypad are received by keyboard interface circuit **144** which "debounces" the keystrokes, producing clean logic signals on lines **146**. These logic signals are fed back to CPU **120** so that it may confirm keystrokes by producing an audible tone through speaker control circuit **150**. Speaker control circuit also generates unique audible signals to indicate other operations, such as the initiation of an injection, or to notify the operator that scanning should begin. A suitable controller is the MC3487, sold by Motorola.

CPU **120** communicates with the powerpack via an RS422 interface circuit **148** which sends and receives digital signals over lines **75** and **76**. Interface circuit **148** also receives and forwards keystrokes directly from keyboard interface **144**. The eight keys on the console form a single, eight bit byte of information (where each bit indicates whether the key is pressed or released). This byte is coupled directly to CPU **120** via a "245" type logical buffer.

+28 Volt DC power is received from the power supplies in the powerpack via lines **152**. A power supply circuit **154** regulates this +28 Volt DC power line into a collection of supply voltages, as needed by the various circuitry in the console. Furthermore, a power inverter circuit converts +12 Volt DC power produced by the power supply circuit **154** into low-current 600 Volt AC power supplies for energizing the liquid crystal display.

Referring to FIG. **5**, the powerhead also includes a circuit board **160** including microprocessor to perform communications with the powerpack **50** (FIG. **2C**). A suitable microprocessor is the 68HC11E2, sold by Motorola, which is a low-cost, minimal functionality microprocessor in the 68000 family. The circuit board receives and forwards keystrokes from the buttons on the keyboard **162** (described above), and electrical pulses indicating movements from the manual knob **163** mounted on the rear of the powerhead. A suitable manual knob is the model 600 thumbwheel, sold by Clarostat of 1 Washington Street, Dover, N.H. 03820. The circuit board also lights and extinguishes the injecting/fault indicator light **49A** and the enabled indicator light **49B**.

The motor **98** is coupled to a gear box which translates rotary motion of the motor to linear translation of the plunger. One suitable motor is the CYMS A2774-2 motor, sold by Barber-Colman, P.O. Box 7040, Rockford, Ill. 61125. The rotation of the motor is detected by optical encoder **166** (encoder **166** essentially comprises a pinwheel which rotates between a light source and a light detector to produce electrical pulses, for example the HEDS-9100 encoder, sold by Hewlett-Packard of 3003 Scott Boulevard, Santa Clara, Calif. 95054). Encoder **166** sends electrical pulses to circuit board **160**, which relays them to powerpack **50**, allowing CPU **52** on the powerpack to monitor movement of the motor.

The position of the plunger is detected by a linear potentiometer **168**, for example the LCPL200, sold by ETI Systems of 215 Via Del Norte, Oceanside, Calif. 92054. The wiper **169** of potentiometer **168** is mechanically coupled to and moves with the plunger **12**. A DC voltage drop is placed

across the potentiometer terminals **170** and **171**, and as a result, an analog voltage representative of the location of the plunger and wiper **169** is produced at the wiper **169**. An A/D converter on circuit board **160** converts this analog voltage to a digital signal which circuit board **160** forwards to the powerpack **50**.

Circuit board **160** also detects the output of two Hall effect sensors **172** and **174**. The powerhead has a removable face plate **42** (FIG. 2B). There are currently two different face plates having differently-sized apertures for accepting differently-sized syringes. Thus, although the face plate need not be removed to replace the syringe, it may be removed to use a different syringe size. Sensor **172** detects whether face plate **42** is open, and if so circuit board **160** sends a message to powerpack **50** which prevents any further injection procedures until the face plate is closed. Sensor **174** detects the size of the face plate in use. Currently, only one of the two face plates includes a magnet which triggers sensor **174**; thus, circuit board can determine which face plate has been installed by determining whether sensor **174** has been triggered. This information is also forwarded to CPU **52** in the powerpack so that CPU **52** may compensate for the different syringe sizes when controlling motor **98** (as described below).

At the direction of CPU **52**, circuit board **160** also controls heater blanket **176**, which heats the contrast fluid in the syringe. Furthermore, circuit board **160** controls movement indicator board **178**. Movement indicator board **178** is mechanically coupled to the plunger **12** and includes two light emitting diodes LEDs **179** which are visible through window **44** on the powerhead (FIG. 2B). LEDs **179** provide the operator with feedback on the position of the plunger, by correlating the position of the diodes with the graduated scale on window **41**. The two sides of the window **41** contain different graduated scales: one calibrated for large syringes and one for small syringes. Depending on the syringe size detected by sensor **174**, the LED next to the appropriate graduated scale is illuminated. Furthermore, as discussed in more detail below, when the plunger is moving, CPU **52** directs circuit board **160** to flash the LED. Also, when the CPU **52** enters its "locked mode" (discussed above), CPU **52** directs circuit board **160** to steadily light the LED. Thus, LEDs **179** provide operator feedback on the plunger position, direction of motion, and the "locked mode".

Referring to FIGS. 6A–6F, an injection protocol will be described from the operator's perspective. The main operating screen is illustrated in FIG. 6A. Box **200**, which is associated with an iconic representation **201** of the powerhead, identifies the current volume of contrast media in the syringe. Box **202**, which is associated with an iconic representation **203** of the syringe, identifies the total volume which has been dispensed during the currently selected protocol. Box **204** identifies the pressure limit pre-selected by the operator for the procedure, and box **206** identifies a scan delay (in seconds), which is the delay from the time the operator initiates an injection (either with the handswitch, a key on the console or a button on the powerhead) until the x ray or magnetic scan of the subject should begin (at the end of this delay. CPU **120** produces a tone indicating to the operator that scanning should begin; alternatively, scanning could be automatically initiated by a suitable electrical connection between the scanner and injector). In the illustrated situation, the syringe contains 180 ml of fluid, 30 ml of which will be used by the currently selected protocol, the pressure limit is 200 psi and there is no scan delay.

In the display illustrated in FIG. 6A, the upper regions of the screen display stored injection protocols. Region **208** identifies protocols which the operator may select, and region **210** gives details of the currently selected protocol. As shown in region **210**, a protocol comprises a number of phases; during each phase the injector produces a pre-programmed flow rate to output a pre-programmed total fluid volume. The illustrated protocol "SERIO VASCUL" has only one phase; however, other protocols which can be selected by the operator have multiple phases. In region **208**, protocols are identified by name and by number of phases; thus, as illustrated, the "LIVER" protocol has 2 phases and the "ABDOMEN PI" protocol has 3 phases.

The user can select protocols, enable an injection, and otherwise navigate through display screens by pressing the buttons on the keypad **34** next to the display. Region **212** of the display is dedicated to identifying the functions available from the buttons on the keypad **34**. Thus, in this display illustrated in FIG. 6A, the user may select the previous or next protocol in the list in region **208** by pressing the buttons next to the words "PREVIOUS PROTOCOL" and "NEXT PROTOCOL", respectively, on the display. The user may also change and store the flow, volume and inject delay values for the current protocol by pressing the button next to "CHANGE VALUES"; doing so will alter the function of the keypad and region **212** of the display, so that the operator may select a value, increment and decrement the value, select characters to form or edit a protocol name, and then return to the display shown in FIG. 6A. From FIG. 6A, the operator may also enter a control panel display (see FIG. 6E, below) to adjust operating parameters and other data. Also, the operator may enter a protocol manager in which the operator may rename or delete protocols, and may determine the order of the protocol list shown in region **208**. Finally, the user may also enable an injection from the display illustrated in FIG. 6A by pressing the button next to "ENABLE".

As shown in FIG. 6B, when the user enables an injection, as a safety measure, the injector first presents a text box **214** which asks the operator whether all of the air has been evacuated from the syringe. Region **212** of the display contains only the words "YES" and "NO", indicating that the operator must answer the question as either yes or no. If the button next to "NO" is pressed, the injection will be cancelled. If the answer is "YES", the injector will proceed to an enabled state, illustrated in FIG. 6C. Here, region **208** of the display indicates the expected duration, and region **212** includes the word "START", "AUTO ENABLE" and "EXIT". If the operator presses the button next to "EXIT", the injector will return to the state illustrated by FIG. 6A. If the operator presses the button next to "AUTO ENABLE", the injector will toggle into and out of the auto-enabled mode, as confirmed by a briefly-displayed box in the center of the screen. If the operator presses the button next to "START" the injection will begin and the injector will move to the state illustrated by FIG. 6D.

While an injection is proceeding, the display shown in FIG. 6D is displayed. In this display, region **208** indicates the total injection time and the volume (in ml) delivered to the patient. Region **212** shows the word "STOP" next to each of the buttons on the keypad **34**, indicating that the operator may stop the injection by pressing any of the buttons (or by pressing the start/stop button **45** on the powerhead, or by pressing the handswitch). In addition, in box **200**, the total volume of fluid in the syringe counts down as fluid in injected into the subject.

After the injection protocol has completed, the injector will return either to the state illustrated by FIG. 6A or to the state illustrated by FIG. 6C. If the operator put the injector

in the auto-enable mode by pressing "AUTO ENABLE" at FIG. 6C, the injector will return to the state illustrated by FIG. 6C. However, if the operator did not put the injector into the auto-enable mode, the injector will return to the state illustrated by FIG. 6A. Thus, by placing the injector in auto-enable mode, the operator can more easily repeat an injection protocol; this can be useful where, for example, the contrast media dissipates relatively rapidly, and multiple images will be taken on the same area of the subject. By using "AUTO ENABLE", the operator may replenish the contrast media just before each image by pressing a single key (or the handswitch), without re-enabling the injector.

As noted above, injection operators may wish to use prefilled syringes for injections. However, prefilled syringes often include extenders which reduce the filled volume of the syringe (syringes of this type are known as "partial pre-filled" syringes). The injector described herein includes a feature for compensating for the reduced volume of partial pre-filled syringes, described below.

As noted above, to set up the injector, the operator may enter the "Control Panel", illustrated in FIG. 6E. In the control panel, the display identifies the current operational settings of the injector. Thus, the control panel includes a box **220** which identifies the current pressure limit, a box **222** which identifies the current language (as noted above, the operator may choose a language for the textual portions of the display), boxes **226** and **228** which identify the current time and date, and a box **230** which identifies the owners registration name and/or number. This information is entered using the keypad and region **212** of the display in the manner discussed above.

An additional box **232** on the "Control Panel" display is used to indicate whether partial pre-filled syringes will be used with the injector. Box **232** will include the word "YES" or "NO", as selected by the operator (as shown in FIG. 6E, when the user attempts to modify this box, region **212** of the display provides a menu with the choices "YES" or "NO").

If the operator has modified box **232** to indicate that partial pre-filled may be used (i.e., box **232** has a "YES"), then the enable procedure described above is modified slightly. If partial pre-filleds may be used, after the operator enables an injection by pressing "ENABLE" at the display of FIG. 6A, the injector presents the screen illustrated in FIG. 6F, in which the operator must identify the pre-filled syringe size by pressing a button next to "50 ml", "65 ml", "75 ml", "100 ml", or "125 ml". Once the operator has identified the pre-filled syringe size, the injector will continue to the display illustrated in FIG. 6B. CPU **52** (FIG. 3) will then compensate for the extender in the syringe, in the manner described below with reference to FIG. 7B.

Referring to FIG. 7A, the program operating in CPU **52** is initiated **240** when the power is turned on. The program first initializes **242** the hardware and software attached in powerpack **50**, powerhead **40** and display **30**. Then, CPU **52** performs **244** diagnostics to ensure that the injector is operating properly; essentially, this involves sending test data to various hardware elements and verifying that the appropriate responses are received.

After these diagnostics have passed, CPU **52** initiates a number of "threads", or parallel processes; thereafter, these processes are time-multiplexed on CPU **52** under control of the above-described USX68K operating system. These threads communicate with the operating system and with each other by "messages" or semaphores—essentially, inter-process communications are placed in a globally accessible area, managed by the operating system, where they can be later retrieved by other threads. The operating system allocates processing time to the threads. Much of the time, a thread will be "inactive", i.e., it will not have any pending operations to perform. The threads are generally written so that, if the thread is inactive, it will notify the operating system of this fact ("return time" to the operating system) so that the operating system can reallocate processing time to another thread.

The operating system allocates processing time to threads in a prioritized, round-robin fashion. Thus, the operating system will provide processing time to each thread generally in turn; if an active, low-priority thread uses more than a maximum amount of processing time, the operating system will interrupt the thread, and provide other, higher priority threads with an opportunity to use processing time. However, a high-priority thread will not be interrupted by lower priority threads, regardless of whether the high-priority thread uses more than the maximum amount of processing time. Under normal operation, most of the threads are inactive, and there is no conflict between threads for processing time; however, in those occasions where there is a conflict, this prioritized system allows the most important threads to continue uninterrupted where necessary. It should be noted, however, that even the highest priority thread (servo thread **254**) occasionally returns time to the operating system (at those moments where an interruption can be tolerated), so that other threads are able to continue their operations even while the highest priority thread is active.

The threads operating in the CPU **52** generally fall into two categories: "communicating" threads which send information into and out of the powerpack **50**, and "operating" threads which generate or process the information sent or received by the powerpack. There are two operating threads: state machine thread **246** and servo thread **254**.

State machine thread **246** directs the console **30** to produce screen displays of the type shown in FIGS. 6A–6E, and also processes button presses by the user. Thread **246** is essentially a state machine, where each "state" corresponds to a display screen, and each operator keystroke produces a state transition. The software in program EPROM **58** (FIG. 3) essentially defines a state transition diagram, identifying specific states, displays associated with those states, and, for each state, the keystrokes or other activity which will cause a transition to another state.

As shown in FIG. 7B, when initiated, thread **246** looks **270** for a message, for example a message from a communications thread indicating that console button was pressed, or a message from the servo thread indicating that the display should be updated to reflect recent injection activity. If no message has been received, the thread returns **272** time to the operating system. However, if a message has been received, the thread uses the software in program EPROM **58** to identify and transition **274** to the new state associated with the received keystroke or activity. In some cases, e.g. where the operator has pressed an invalid button, the new state will be the same as the old state; in other cases, the new state will be a different state. If the new state is a different state, the state machine thread sends messages to the appropriate communication thread to modify **276** the screen to reflect the new state. In addition, the state machine thread may send **278** messages to the servo thread, e.g. to notify the servo thread that the operator has pressed a button which starts a protocol. When this is completed, the state machine returns **280** to the operating system.

When a start message is sent to the servo thread, the thread sending the message initiates one or more global

variables to indicate the kind of movement requested. Eight global variables (variables managed by the operating system and accessible by all threads), organized into four pairs, are used for this purpose. Each pair of variables identifies a desired new position for the plunger and a speed at which the plunger should move to that position. Four protocol phases can be described by the four variable pairs, and thus may be executed in one message to the servo thread. Thus, when the state machine thread sends **278** a message to the servo thread, it computes one or more desired ending positions and speeds from the selected protocol, and places the computed values into global variables.

Referring to FIG. 7C, when initiated by the operating system, the servo thread **254** first checks **282** for a message telling the servo to start motion of the plunger. If no message is received, the servo thread returns **284** time to the operating system. If, however, a start message has been received, the servo thread starts **286** the motor to move to the desired position indicated by a global variable at the desired speed indicated by a global variable. At this point, the servo thread enters a loop; during each iteration the loop checks **288** if the plunger has arrived at the desired position (the plunger position is determined by the powerhead receive thread **260** as illustrated in FIG. 7E, below), and if so, the loop terminates and the servo thread stops **290** the motor and returns. However, if the plunger has not arrived at the desired position, the servo thread checks **292** if the speed of the motor is correct (the motor speed is measured by an interrupt routine illustrated in FIG. 7D, below). If the motor speed is incorrect, it is corrected **294** by adjusting the motor voltage. Once these steps are completed, the servo thread allows **296** the operating system three time slices (about 21 milliseconds) to operate other processes, after which it returns to step **288** to close the loop.

Referring to FIG. 7D, as noted above, the motor speed is measured by an interrupt routine. When a pulse is detected from the optical encoder **166** (FIG. 5) attached to the motor **98**, the processor in the powerhead circuit board **160** causes an interrupt to travel on line **71** to CPU. **52**. When this interrupt is received **300**, the interrupt routine computes **302** the time elapsed from the previous count interrupt, and from this elapsed time computes **304** the plunger speed. This speed value is stored **306** in a global variable (where it can be accessed by the servo routine), and the interrupt is done **308**.

Referring to FIG. 7E, the powerhead receive thread **260** is responsible for receiving messages from the powerhead and performing a number of tasks in response, including relaying manual movements of the plunger to the servo thread and (as noted above) relaying position measurements to the servo thread during movement of the plunger.

When the operating system initiates **260** the powerhead thread, the thread first checks **310** for any messages; if none have been received, the thread returns **312** time to the operating system. However, if the thread has received a message, it determines **312** what the message is and acts appropriately (this determination is illustrated for clarity as a multi-way branch, but in the code in the fiche appendix it is implemented as a series of individual tests performed on in sequence). The message may contain an error message **314**, a manual knob movement **316**, a linear potentiometer reading **318** (which are periodically generated by the powerhead), a fill button reading **320** (which is periodically generated by the powerhead), a start/stop button press **322**, or several others (multiple messages may be received at one time).

As shown in FIG. 7E, if the message contains a linear potentiometer reading **318**, the reading is converted **324** into an equivalent volume (using calibration readings stored in EEPROM **62**). Then, an offset value (which compensates for the presence of the extender in a partial pre-filled syringe), is subtracted **326** from the computed volume, and the result is stored in a global variable, where it can be later accessed by the servo thread at step **288** (FIG. 7C). The offset value used in step **326** is generated when the user identifies the partial pre-filled size in response to the display shown in FIG. 6F; if partial pre-filled syringes are not used, the offset is set to a constant zero value. Once the adjusted volume is stored, the powerhead thread returns **328** time to the operating system.

As shown in FIG. 7F, when a fill button reading is received (i.e., the received message indicates the state of buttons **46**, **47** and **48** on the keyboard **162** of the powerhead), the powerhead thread first determines **330** which button, or buttons, are pressed.

If a "fast" button **48** and the forward button **46** or reverse button **47** are pressed **332**, the thread first determines **334** whether the motor is at its maximum, latching speed (by reading the global variable indicating the motor speed, as produced by the interrupt routine illustrated in FIG. 7D). If not, the thread increases **336** the motor speed in the indicated direction—by increasing the value of the global variable identifying the desired speed, setting the global variable identifying the desired location to identify the end of the syringe (and sending a start servo message to the servo thread if the motor is not already running)—and returns **338** time to the operating system. If, however, the motor has reached its latching speed, then the thread determines **340** if buttons were pressed the last time a fill button reading was processed. If so, then the operator has accelerated the motor to its maximum speed and is continuing to hold down the buttons. In this situation, the motor should continue running at its maximum speed; therefore, the thread simply returns **338** time to the operating system. If, however, buttons were not pressed last time, then the operator latched the motor at maximum speed, released the buttons, and some time later pressed a button in an attempt to stop the motor. Thus, in this situation, the thread stops **342** the motor (by setting the global variable indicating the desired speed to zero), and returns **338** time to the operating system.

If the operator is pressing **344** the forward or reverse buttons alone, or any other combination of buttons, the thread first determines **346** if the motor is running (by checking the value of the global variable indicating the motor speed). If the motor not running, then a single keystroke will not start it running, so the thread simply returns **338** to the operating system. If, however, the motor is running, then the thread determines **348** if buttons were pressed the last time a fill button reading was processed. If buttons were pressed last time, then the operator is merely trying to keep the motor running at its current speed by holding a button down; therefore, in this situation, the thread simply returns **338** to the operating system, allowing the motor to continue running. If, however, buttons were not pressed last time, then the operator latched the motor at maximum speed, released the buttons, and some time later pressed a button in an attempt to stop the motor. Thus, in this situation, the thread stops **342** the motor (by setting the global variable indicating the desired speed to zero), and returns **338** time to the operating system.

If no buttons are pressed **352**, the thread simply determines **354** if the motor is at its latching speed. If not, the thread stops **356** the motor and returns time to the operating system. Otherwise, the thread returns **338** directly, allowing the motor to continue running at the latching speed.

Referring to FIG. 7G, manual motion can also be created by turning the manual knob **163** (FIG. 5) mounted on the rear of the powerhead. As noted above, the powerhead CPU **160** regularly reports movements of the manual knob to the powerpack CPU **52**. This report identifies the direction of rotation and the number of electrical pulses received from the knob since the last report (more pulses indicating greater speed of rotation). When a manual knob message is received **316**, the powerhead receive thread first computes **340** a desired plunger speed from the number of pulses identified in the message, and computes **342** a desired end position from the number of pulses and the direction of rotation of the knob. These are then stored **344** in global variables accessible to the servo thread as described above. If the motor is not already running, the powerhead receive thread also sends a servo start message to the servo thread. Then the thread returns **346** time to the operating system.

The invention has been described with reference to a specific embodiment. However, it will now be understood that various modifications and alterations can be made to this specific embodiment without departing from the inventive concepts embodied therein. For example, the manual motion knob **163** may be replaced by any other control which allows velocity and direction control, for example by a button or knob which can be rotated or rocked to multiple positions corresponding to various velocities and directions of motions, or a set of buttons or knobs which allow the operator to separately select a desired velocity with one button or knob and a desired direction with another button or knob. Therefore, this specific embodiment is to be interpreted as exemplary and not limiting, with the scope of protection being determined solely from the following claims.

What is claimed is:

1. An injector of the type having a motor which advances and retracts a plunger located within a syringe toward and away from a nozzle located in the front of the syringe to inject fluid into or out of an animal subject, adapted for use with a syringe including an extender attached to said plunger, comprising:

a control circuit which causes said motor to move, said control circuit tracking the location of said motor while moving said motor, and

a memory storing an offset value representative of the length of the extender which is attached to said plunger, wherein

said control circuit computes a value indicative of the location of said plunger within said syringe by relating said stored offset value to the tracked location of said motor, and ceases motion of said plunger when said computed value indicates that said plunger is at an end of said syringe.

2. The injector of claim **1** further comprising

a display, and

a keypad usable by an operator to control said injector,

wherein said control circuit generates and stores said offset value by controlling said display to request, from an operator, information sufficient to compute the length of the extender which is attached to said plunger, monitoring keystrokes on said keypad to determine said information, deriving said offset value therefrom, and storing the derived offset value in said memory.

3. The injector of claim **1** further comprising

a detector located proximate to said syringe for detecting the length of the extender which is attached to said plunger from physical indicia on the syringe or extender and generating an electrical signal representative of the detected length, wherein

said control circuit is responsive to said electrical signal, and generates and stores an offset value corresponding to the detected length represented by said electrical signal.

4. A method of controlling an injector of the type having a motor which advances and retracts a plunger located within a syringe toward and away from a nozzle located in the front of the syringe to inject fluid into or out of an animal subject, adapted for use with a syringe including an extender attached to said plunger, comprising:

storing an offset value representative of the length of the extender which is attached to said plunger,

causing said motor to move,

tracking the location of said motor while moving said motor,

computing a value indicative of the location of said plunger within said syringe by relating said stored offset value to the tracked location of said motor, and

ceasing motion of said plunger when said computed value indicates that said plunger is at an end of said syringe.

5. The method of claim **4** further comprising

requesting, from an operator, information sufficient to compute the length of the extender which is attached to said plunger, and

deriving said offset value from said information from said operator.

6. The method of claim **4** further comprising

detecting the length of the extender which is attached to said plunger from physical indicia on the syringe or extender and generating an electrical signal representative of the detected length, and

deriving said offset value from the detected length represented by said electrical signal.

7. An injector of the type having a motor which advances and retracts a plunger located within a syringe toward and away from a nozzle located at a distal end of the syringe to inject fluid into or out of an animal subject, adapted for use with syringe assemblies which have differing capacities, comprising:

a detector located proximate to a syringe installed on said injector for detecting a physical indicia on said syringe related to the capacity of said syringe, and generating an electrical signal representative of said physical indicia, and

a control circuit which causes said motor to move and tracks the location of said motor while moving said motor, wherein said control circuit computes the location of a plunger within said syringe relative to an end of said syringe, by relating said electrical signal to the tracked location of said motor.

8. The injector of claim **7** wherein said control circuit ceases motion of said motor and plunger when a location of said plunger computed by said control circuit indicates that said plunger has arrived at an end of said syringe.

9. The injector of claim **7** wherein said electrical signal represents the length of an extender which is attached to said plunger within said syringe.

10. A method of controlling an injector of the type having a motor which advances and retracts a plunger located within a syringe toward and away from a nozzle located at an end of the syringe to inject fluid into or out of an animal subject, adapted for use with syringe assemblies which have differing capacities, comprising:

detecting a physical indicia on a syringe installed on said injector, said indicia being related to the capacity of

said syringe, and generating an electrical signal representative of said physical indicia,

causing said motor to move,

tracking the location of said motor while moving said motor, and

computing the location of a plunger within said syringe relative to an end of said syringe by relating said electrical signal to the tracked location of said motor.

11. The method of claim 10 further comprising:

ceasing motion of said plunger when a computed location of said plunger indicates that said plunger has arrived at an end of said syringe.

12. The method of claim 10 wherein said electrical signal represents the length of an extender which is attached to said plunger.

* * * * *

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United States Patent [19]

Niehoff

[11] Patent Number: 5,928,197

[45] Date of Patent: Jul. 27, 1999

[54] **CONTROLLING PLUNGER DRIVES FOR FLUID INJECTIONS IN ANIMALS**

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[73] Assignee: **Liebel-Flarsheim Company**, Cincinnati, Ohio

[21] Appl. No.: **08/919,610**

[22] Filed: **Aug. 28, 1997**

Related U.S. Application Data

[63] Continuation of application No. 08/494,795, Jun. 26, 1995, Pat. No. 5,662,612, which is a continuation of application No. 08/157,823, Nov. 24, 1993, abandoned.

[51] **Int. Cl.**[6] **A61M 37/00**

[52] **U.S. Cl.** **604/155**; 604/151; 417/15; 417/63

[58] **Field of Search** 604/67, 131, 151, 604/154, 155; 417/15, 33, 42, 43, 445, 63

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Primary Examiner—Todd E. Manahan

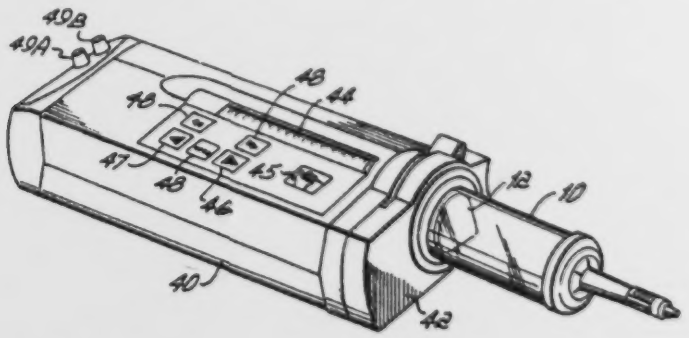
Attorney, Agent, or Firm—Wood, Herron & Evans, L.L.P.

[57] **ABSTRACT**

A computer-controlled injector of the type having a motor which advances and retracts a plunger located within a syringe housing toward and away from a nozzle located in the front of the syringe to inject fluid into or out of an animal subject. Manual motion is induced by operating a manual motion control; the operator can manipulate the control to indicate the desired direction and velocity of motion. The manual motion control also has a locking mode in which manual motion of the plunger will continue once initiated without requiring the operator to continue manipulating the manual motion control. The injector performs injections in accordance with one of several pre-programmed protocols, and automatically tracks the fluid volume remaining. The injector compensates for plunger extenders found in some partially pre-filled syringes by applying a stored offset value to the computed plunger position.

28 Claims, 11 Drawing Sheets

Microfiche Appendix Included
(7 Microfiche, 613 Pages)



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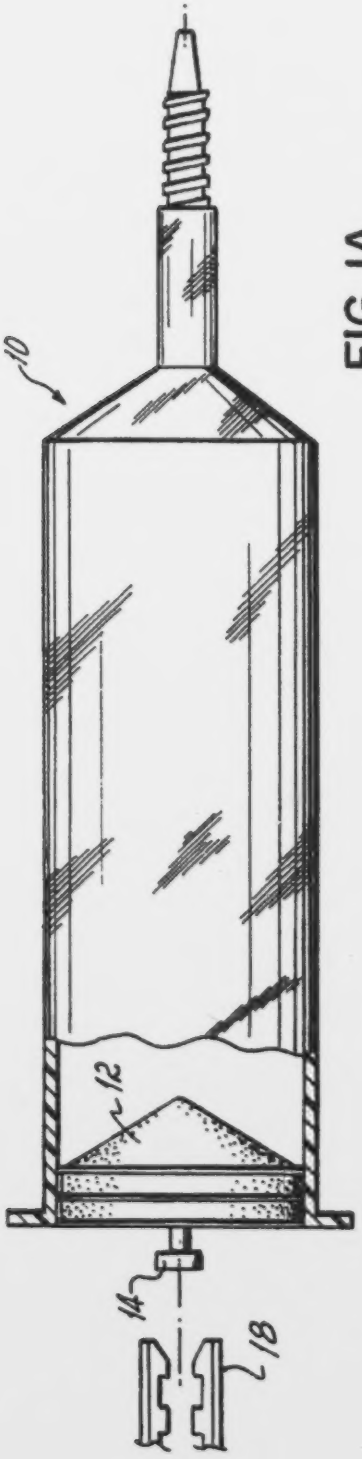


FIG. IA

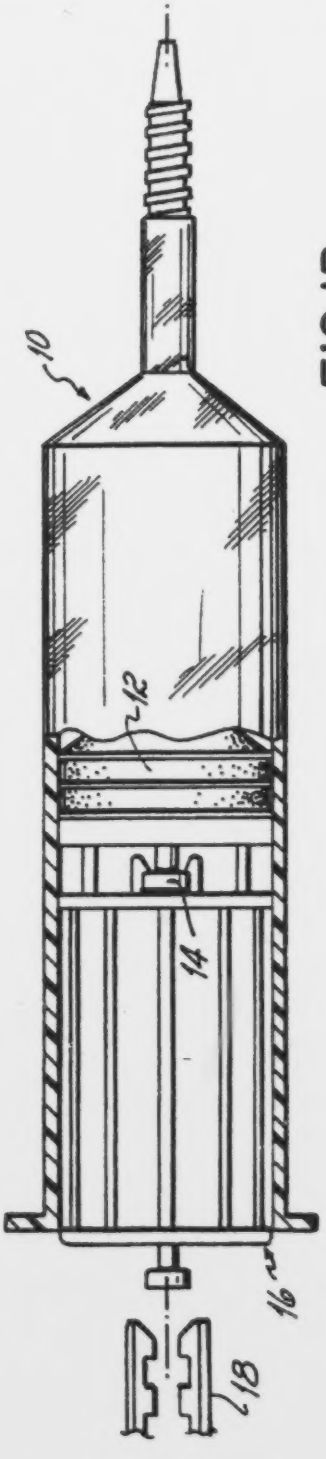


FIG.IB

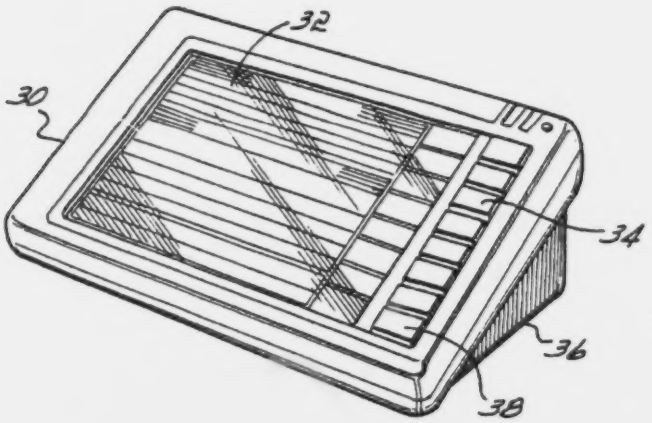


FIG. 2A

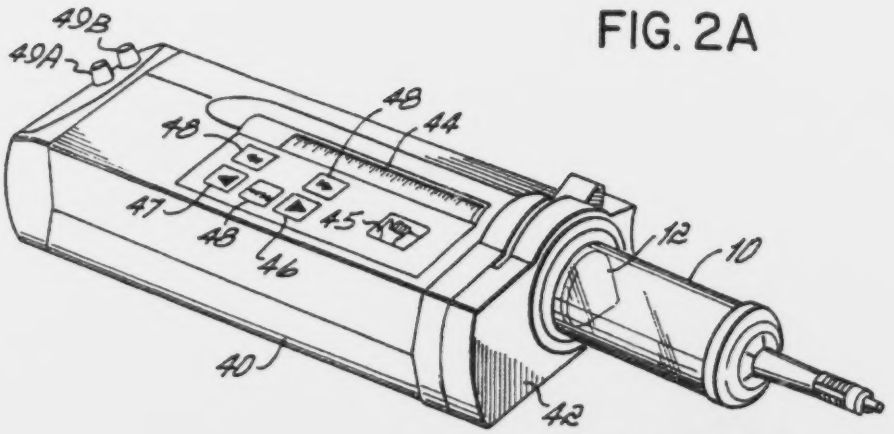


FIG. 2B

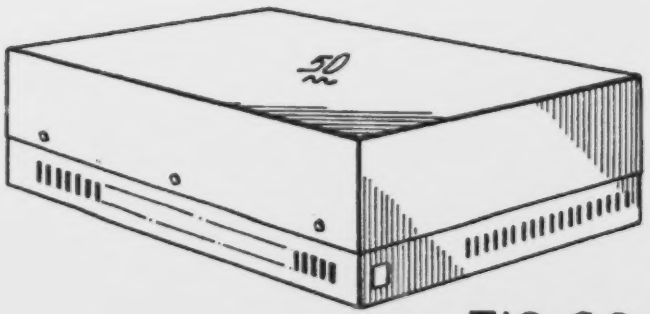


FIG. 2C

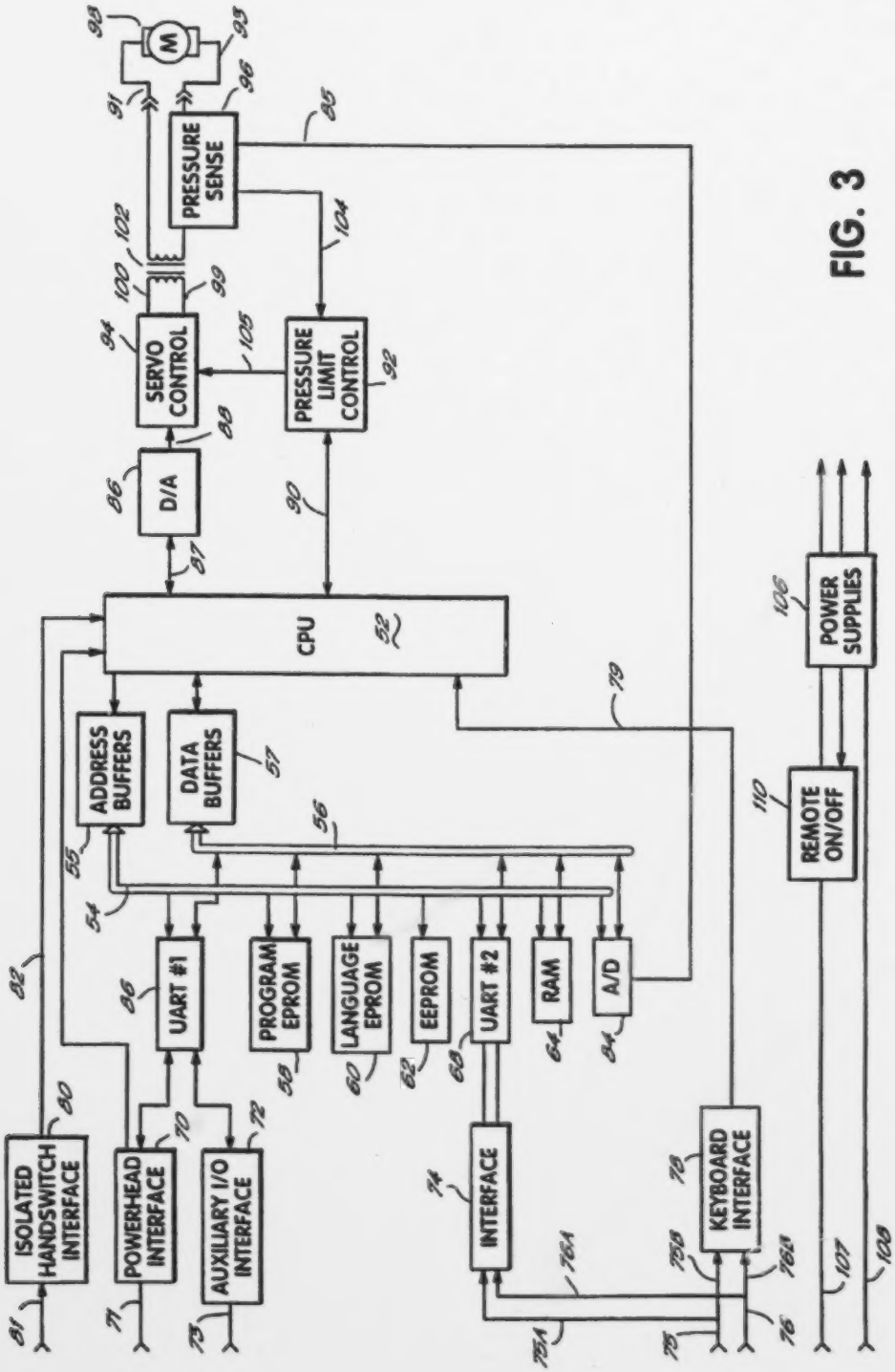
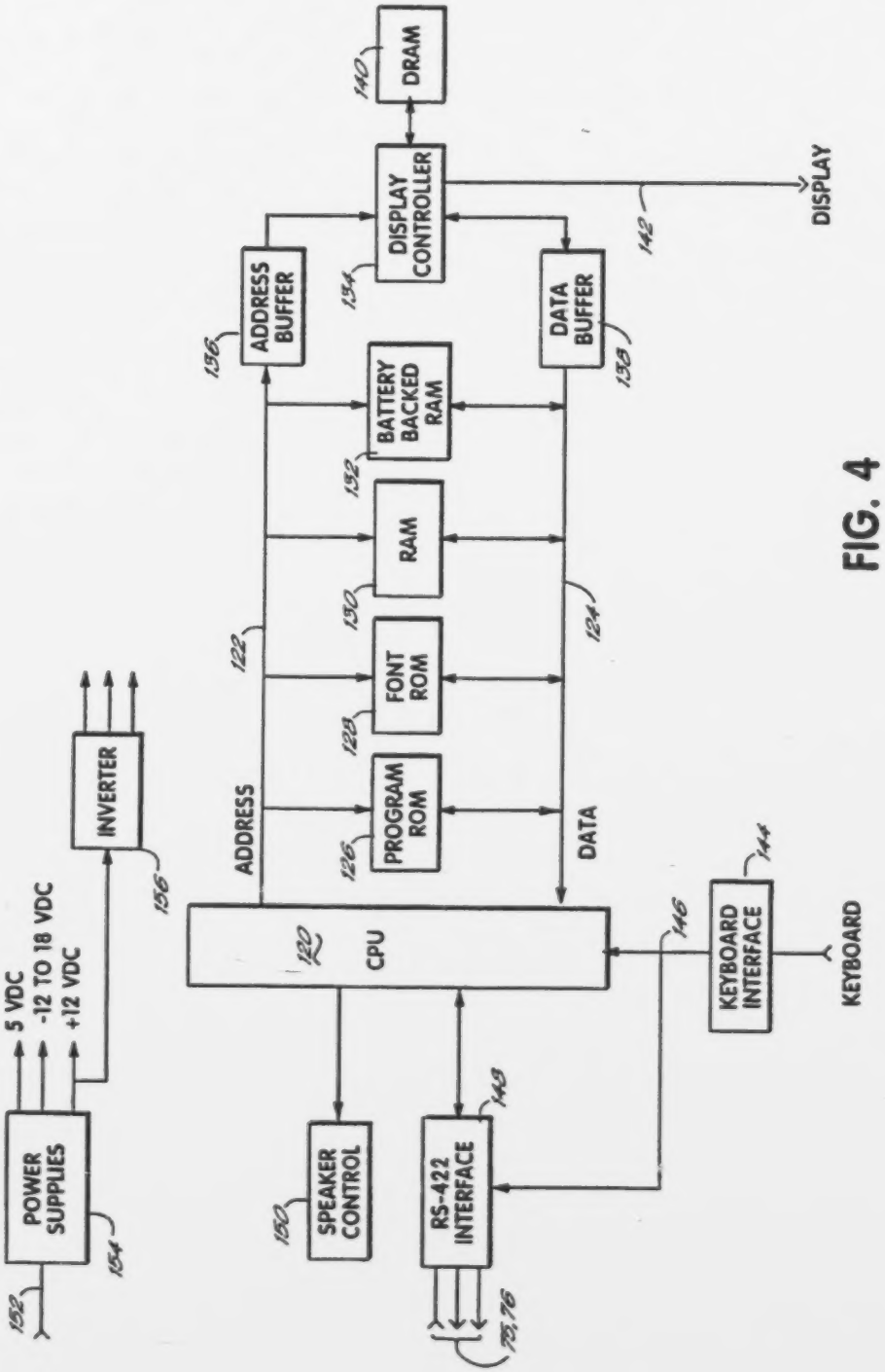

M
PRESSURE SENSE
SERVO CONTROL
PRESSURE LIMIT CONTROL
D/A
CPU
ADDRESS BUFFERS
DATA BUFFERS
UART #1
PROGRAM EPROM
LANGUAGE EPROM
EEPROM
UART #2
RAM
A/D
ISOLATED HANDSWITCH INTERFACE
POWERHEAD INTERFACE
AUXILIARY I/O INTERFACE
INTERFACE
KEYBOARD INTERFACE
POWER SUPPLIES
REMOTE ON/OFF

FIG. 3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DISPLAY
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DATA BUFFER
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RAM
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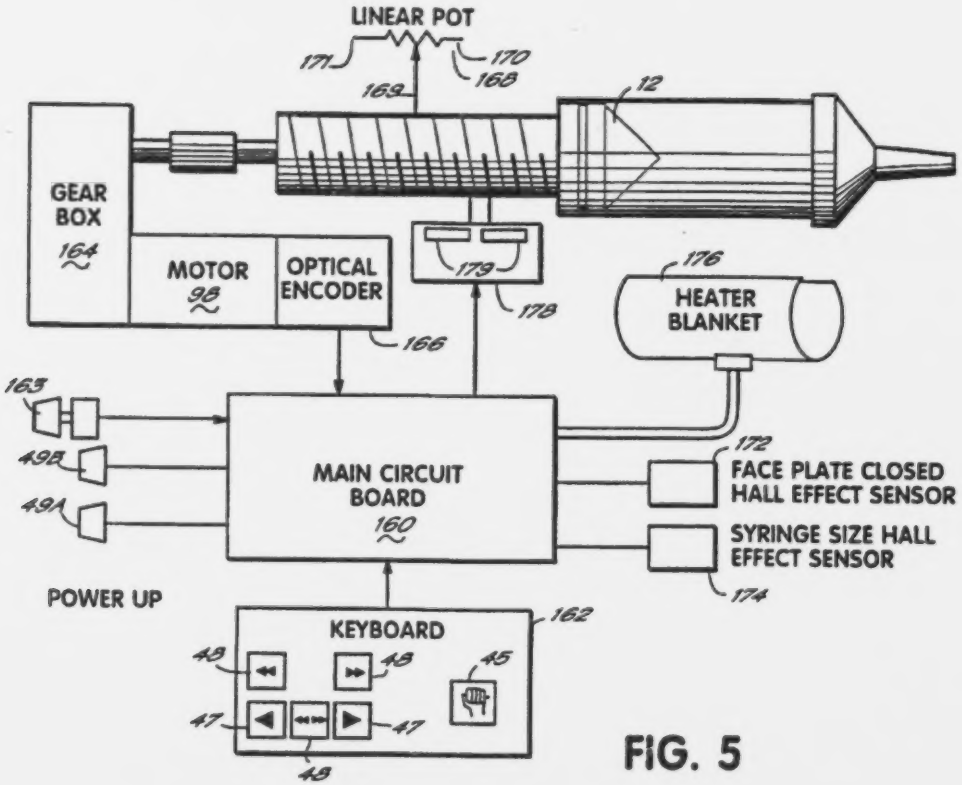
FONT ROM
128
PROGRAM ROM
126
ADDRESS
122
DATA
124
CPU
120
INVERTER
156
5 VDC
-12 TO 18 VDC
+12 VDC
POWER SUPPLIES
154
152
SPEAKER CONTROL
150
RS-422 INTERFACE
148
75,76
KEYBOARD INTERFACE
144
146
KEYBOARD

FIG. 4


LINEAR POT
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MOTOR
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OPTICAL ENCODER
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163
49B
49A
MAIN CIRCUIT BOARD
160
172
FACE PLATE CLOSED HALL EFFECT SENSOR
SYRINGE SIZE HALL EFFECT SENSOR
174
POWER UP
KEYBOARD
162
43
45
47
49

FIG. 5

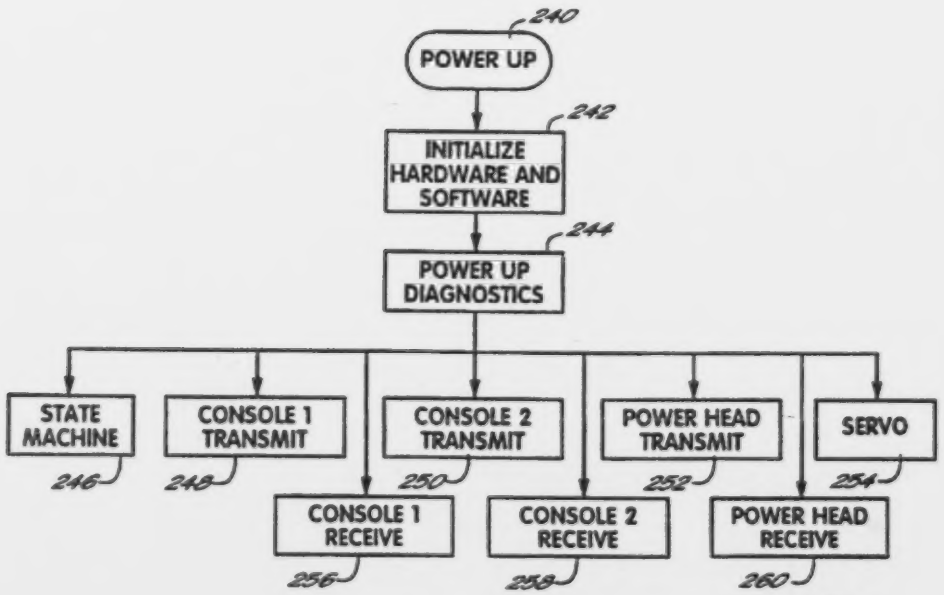
240
POWER UP
242
INITIALIZE HARDWARE AND SOFTWARE
244
POWER UP DIAGNOSTICS
STATE MACHINE
246
CONSOLE 1 TRANSMIT
248
CONSOLE 2 TRANSMIT
250
POWER HEAD TRANSMIT
252
SERVO
254
CONSOLE 1 RECEIVE
256
CONSOLE 2 RECEIVE
258
POWER HEAD RECEIVE
260

FIG.7A

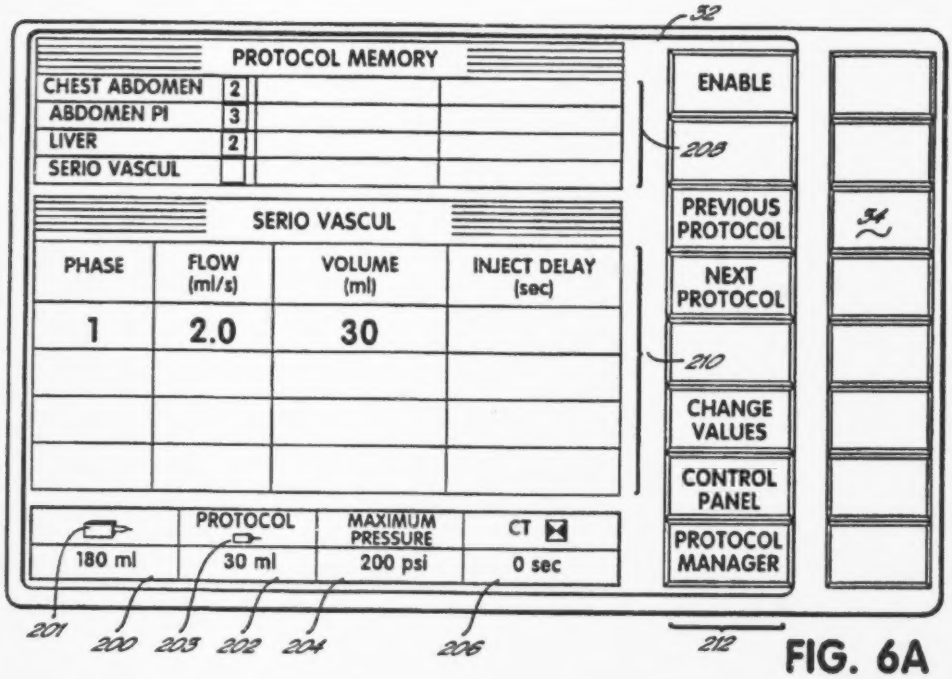
32
PROTOCOL MEMORY
CHEST ABDOMEN 2
ABDOMEN PI 3
LIVER 2
SERIO VASCUL
SERIO VASCUL
PHASE
FLOW (ml/s)
VOLUME (ml)
INJECT DELAY (sec)
1
2.0
30
180 ml
PROTOCOL
30 ml
MAXIMUM PRESSURE
200 psi
CT
0 sec
ENABLE
208
PREVIOUS PROTOCOL
NEXT PROTOCOL
210
CHANGE VALUES
CONTROL PANEL
PROTOCOL MANAGER
34
201
200
203
202
204
206
212

FIG. 6A

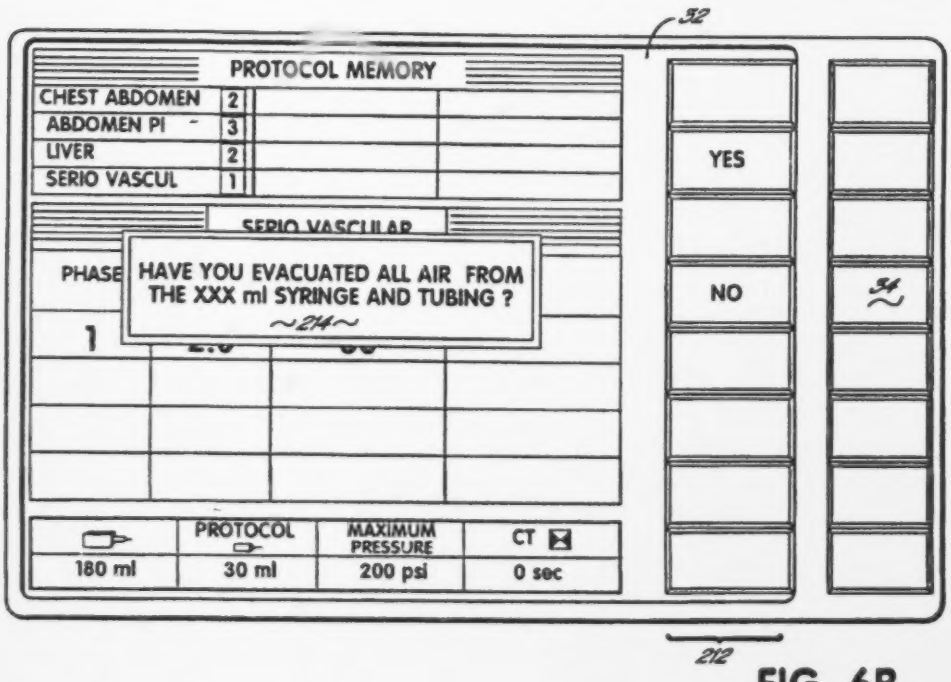
32
PROTOCOL MEMORY
CHEST ABDOMEN 2
ABDOMEN PI 3
LIVER 2
SERIO VASCUL 1
HAVE YOU EVACUATED ALL AIR FROM THE XXX ml SYRINGE AND TUBING ?
214
PHASE
1
180 ml
PROTOCOL
30 ml
MAXIMUM PRESSURE
200 psi
CT
0 sec
YES
NO
34
212

FIG. 6B

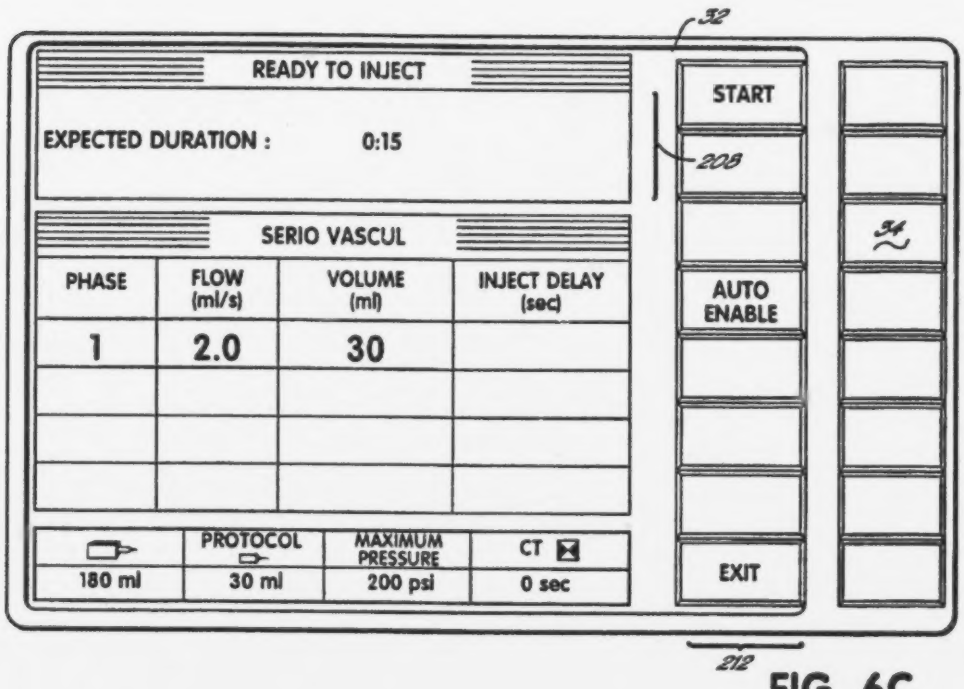
32
READY TO INJECT
EXPECTED DURATION : 0:15
SERIO VASCUL
PHASE
FLOW (ml/s)
VOLUME (ml)
INJECT DELAY (sec)
1
2.0
30
PROTOCOL
MAXIMUM PRESSURE
CT
180 ml
30 ml
200 psi
0 sec
START
208
34
AUTO ENABLE
EXIT
212

FIG. 6C

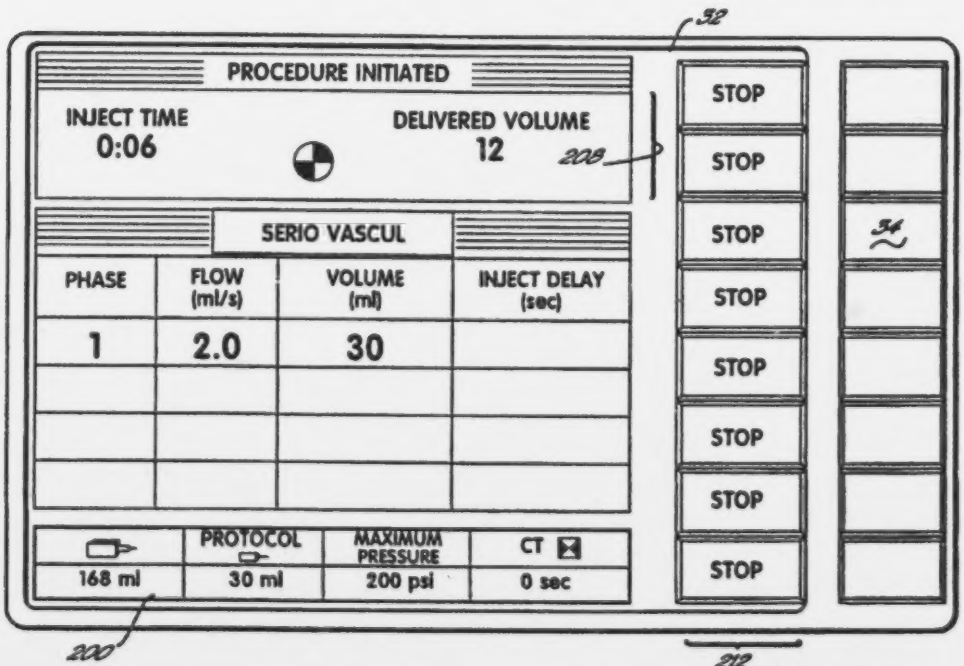
32
PROCEDURE INITIATED
INJECT TIME
0:06
DELIVERED VOLUME
12
208
SERIO VASCUL
PHASE
FLOW (ml/s)
VOLUME (ml)
INJECT DELAY (sec)
1
2.0
30
PROTOCOL
MAXIMUM PRESSURE
CT
168 ml
30 ml
200 psi
0 sec
STOP
34
200
212

FIG. 6D

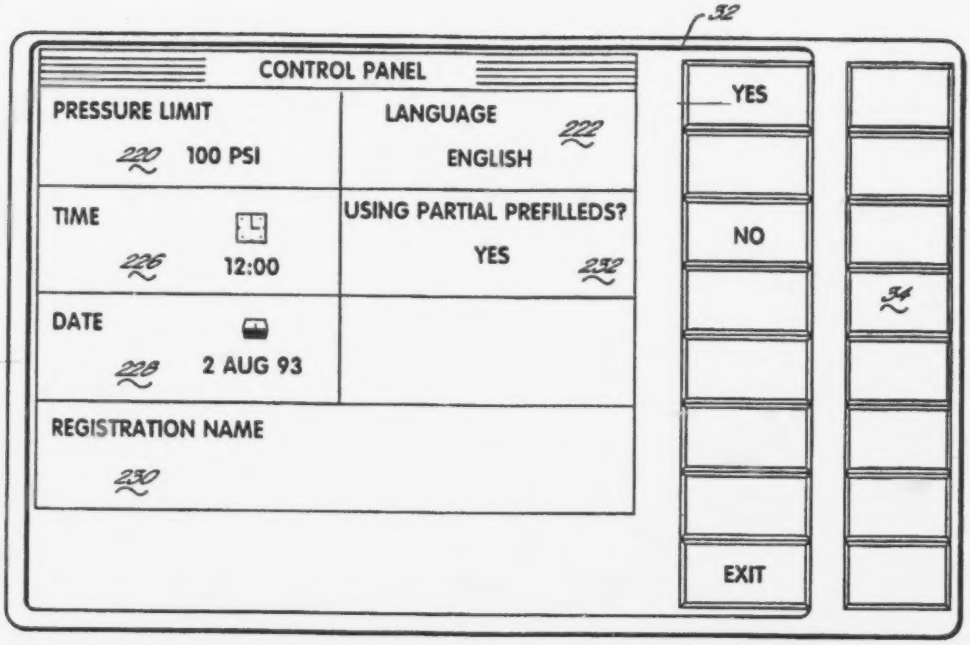
32
CONTROL PANEL
PRESSURE LIMIT
220
100 PSI
LANGUAGE
222
ENGLISH
TIME
226
12:00
USING PARTIAL PREFILLEDS?
YES
232
DATE
228
2 AUG 93
REGISTRATION NAME
230
YES
NO
EXIT
34
212

FIG. 6E

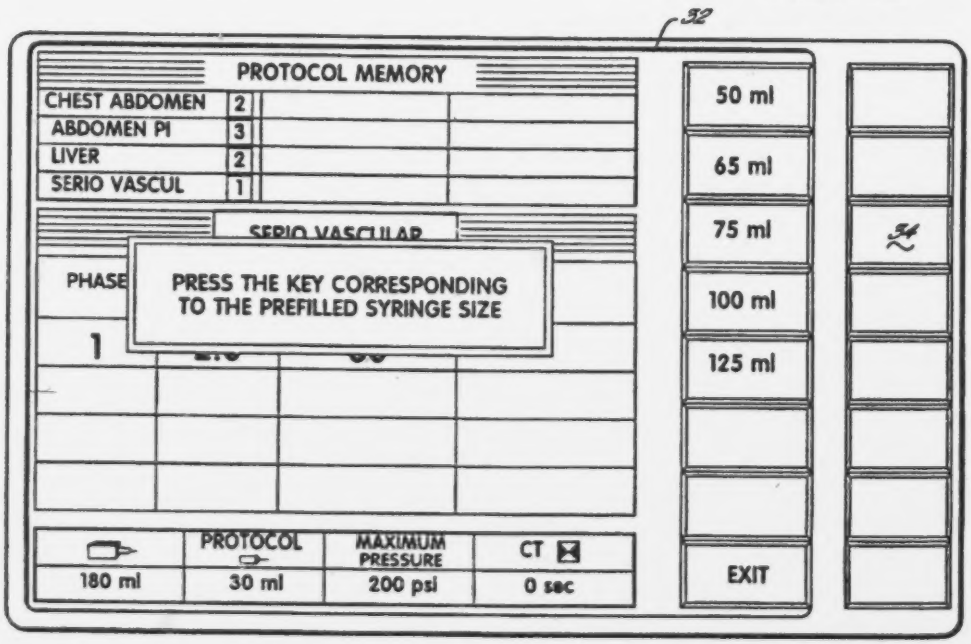
32
PROTOCOL MEMORY
CHEST ABDOMEN 2
ABDOMEN PI 3
LIVER 2
SERIO VASCUL 1
PRESS THE KEY CORRESPONDING TO THE PREFILLED SYRINGE SIZE
PHASE
1
PROTOCOL
MAXIMUM PRESSURE
CT
180 ml
30 ml
200 psi
0 sec
50 ml
65 ml
75 ml
100 ml
125 ml
EXIT
34

FIG. 6F

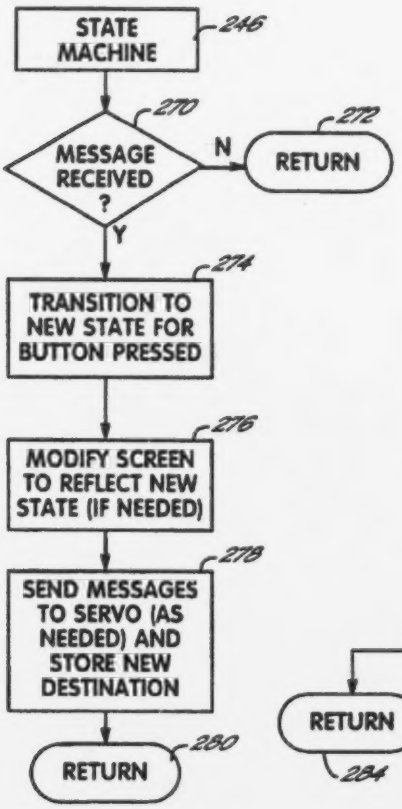
STATE MACHINE
246
270
MESSAGE RECEIVED ?
N
272
RETURN
Y
274
TRANSITION TO NEW STATE FOR BUTTON PRESSED
276
MODIFY SCREEN TO REFLECT NEW STATE (IF NEEDED)
278
SEND MESSAGES TO SERVO (AS NEEDED) AND STORE NEW DESTINATION
RETURN
280

FIG.7B

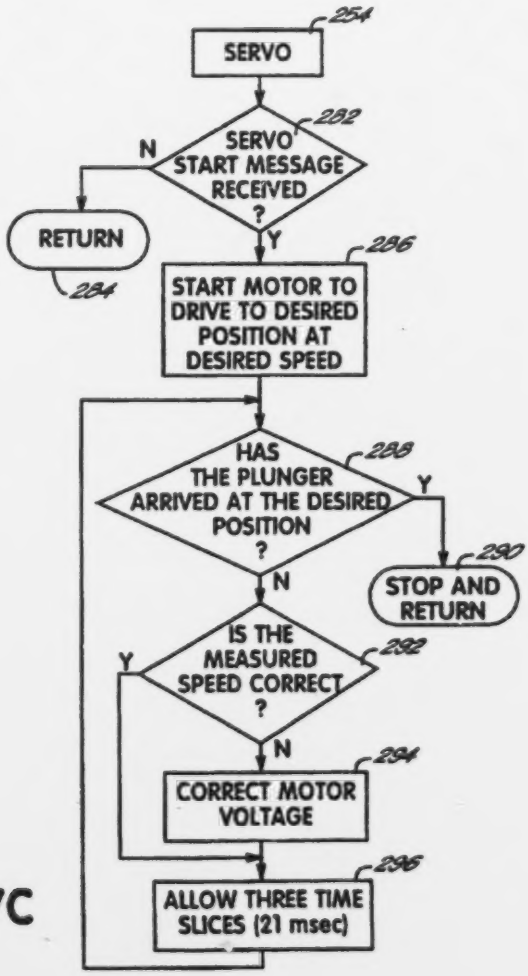
SERVO
254
282
SERVO START MESSAGE RECEIVED ?
N
RETURN
284
Y
286
START MOTOR TO DRIVE TO DESIRED POSITION AT DESIRED SPEED
288
HAS THE PLUNGER ARRIVED AT THE DESIRED POSITION ?
Y
290
STOP AND RETURN
N
292
IS THE MEASURED SPEED CORRECT ?
Y
N
294
CORRECT MOTOR VOLTAGE
296
ALLOW THREE TIME SLICES (21 msec)

FIG.7C

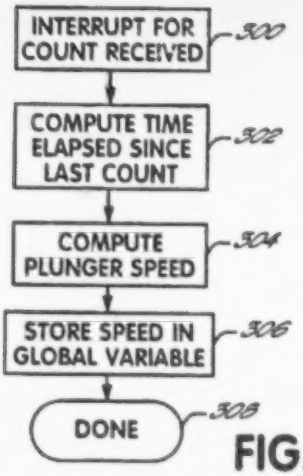
INTERRUPT FOR COUNT RECEIVED
300
COMPUTE TIME ELAPSED SINCE LAST COUNT
302
COMPUTE PLUNGER SPEED
304
STORE SPEED IN GLOBAL VARIABLE
306
DONE
308

FIG.7D

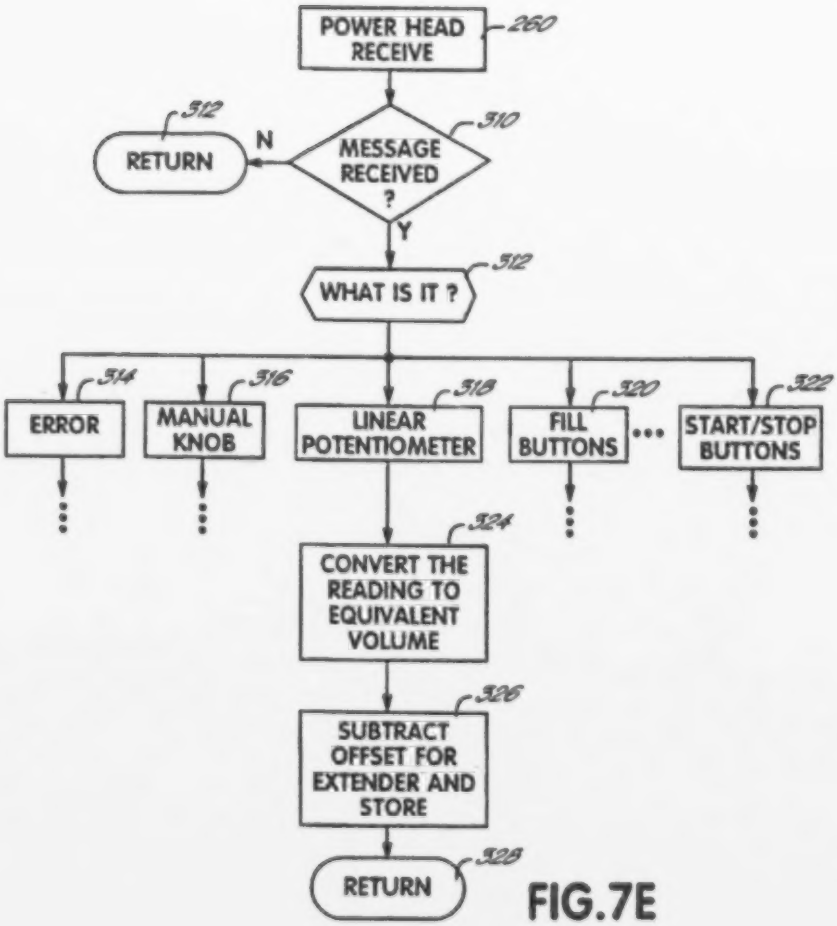
POWER HEAD RECEIVE
260
MESSAGE RECEIVED ?
310
N
RETURN
312
Y
WHAT IS IT ?
312
ERROR
314
MANUAL KNOB
316
LINEAR POTENTIOMETER
318
FILL BUTTONS
320
START/STOP BUTTONS
322
CONVERT THE READING TO EQUIVALENT VOLUME
324
SUBTRACT OFFSET FOR EXTENDER AND STORE
326
RETURN
328

FIG.7E

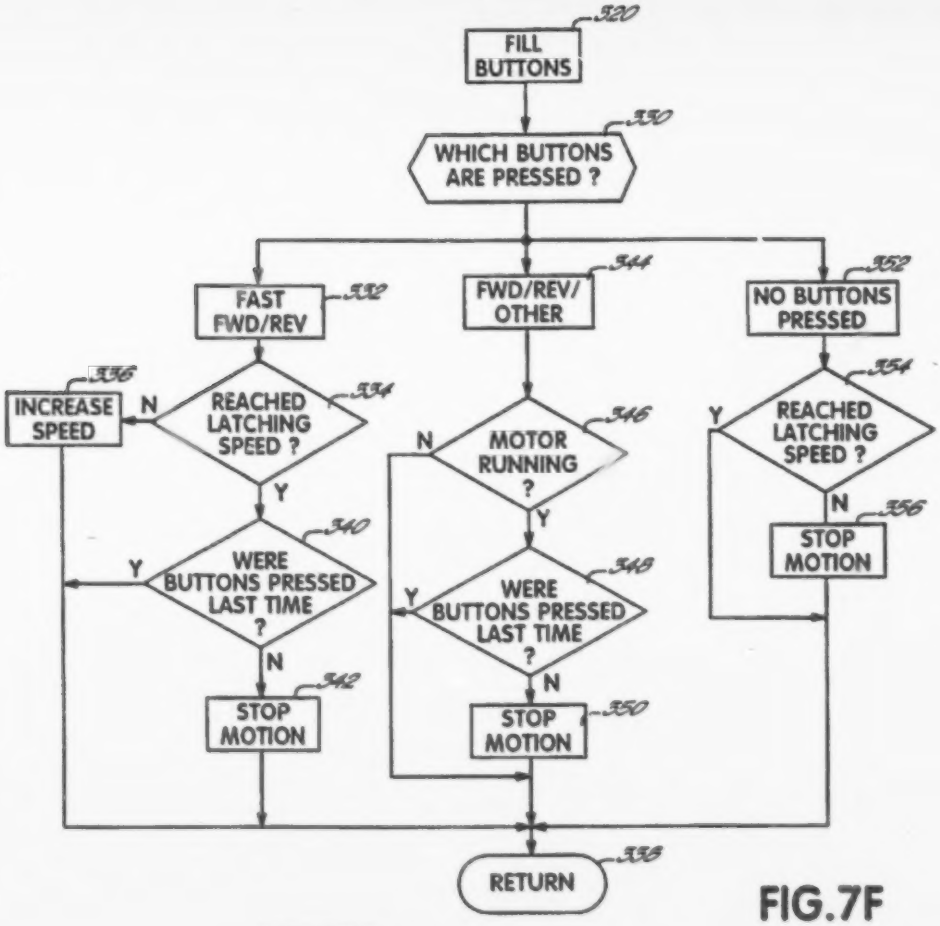
320
FILL BUTTONS
330
WHICH BUTTONS ARE PRESSED ?
FAST FWD/REV
332
FWD/REV/ OTHER
344
NO BUTTONS PRESSED
352
INCREASE SPEED
336
N
REACHED LATCHING SPEED ?
334
Y
N
MOTOR RUNNING ?
346
Y
N
REACHED LATCHING SPEED ?
354
Y
N
STOP MOTION
356
Y
WERE BUTTONS PRESSED LAST TIME ?
340
N
STOP MOTION
342
Y
WERE BUTTONS PRESSED LAST TIME ?
348
N
STOP MOTION
350
RETURN
338

FIG.7F

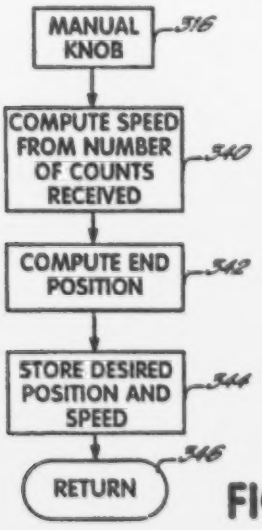
MANUAL KNOB
316
COMPUTE SPEED FROM NUMBER OF COUNTS RECEIVED
340
COMPUTE END POSITION
342
STORE DESIRED POSITION AND SPEED
344
RETURN
346

FIG.7G

CONTROLLING PLUNGER DRIVES FOR FLUID INJECTIONS IN ANIMALS

CROSS REFERENCE TO RELATED APPLICATIONS

This is a continuation application of application Ser. No. 08/494,795 filed on Jun. 26, 1995, for CONTROLLING PLUNGER DRIVES FOR FLUID INJECTIONS IN ANIMALS which issued Sep. 2, 1997 as U.S. Pat. No. 5,662,612 which is a continuation of application Ser. No. 08/157,823 filed on Nov. 24, 1993, which is now abandoned.

This application is related to previously-filed U.S. patent application Ser. No. 07/881,782 of Charles S. Neer et al., filed May 11, 1992 for METHOD AND APPARATUS FOR INJECTING FLUID INTO ANIMALS AND DISPOSABLE FRONT LOADABLE SYRINGE THEREFOR, which is assigned to the same entity as this application.

REFERENCE TO MICROFICHE APPENDIX

A microfiche appendix is attached to this application (7 pages, 613 frames). The software in this appendix is subject to copyright protection. The copyright owner has no objection to reproduction of the appendix in the form that it appears in the U.S. Patent and Trademark Office, but reserves all other rights under copyright law.

BACKGROUND OF THE INVENTION

Injectors are devices that expel fluid, such as radiopaque media (contrast fluid) used to enhance x-ray or magnetic images, from a syringe, through a tube, and into an animal subject. Injectors are typically provided with an injector unit, adjustably fixed to a stand or support, having a plunger drive that couples to the plunger of the syringe and may move the plunger forward to expel fluid into the tube, or move the plunger rearward to draw fluid into the syringe to fill it.

Injectors often include control circuits for controlling the plunger drive so as to control the rate of injection and amount of fluid injected into the subject. Typically, the control circuit includes one or more manual switches which allow a user to manually actuate the plunger drive to move the plunger into or out of the syringe; typically the user holds down a "forward" or "reverse" drive switch to move the plunger in the indicated direction.

To reduce the risk of infection, in a typical injection procedure the syringe is only used once, and is disposed after use. In some cases, the syringe is inserted into the injector empty. The empty syringe is filled by retraction of the plunger while the interior of the syringe communicates with a supply of the contrast fluid via an injection tube connected between the nozzle of the syringe and the supply of media. Then, bubbles are removed from the syringe, and the injection is performed. At the end of the procedure, the syringe plunger typically is forward, as is the plunger drive.

In some injectors, the syringe can only be removed or replaced while the plunger drive is fully retracted. As illustrated in FIG. **1A**, typically an empty syringe **10** is filled with sterile air, with the plunger **12** at the fully retracted position as shown. The plunger drive includes a jaw **18** designed to engage and disengage a button **14** on the rear side of the plunger while the plunger is in this fully-retracted position. Before an empty new syringe can be filled, it is necessary that the plunger be moved fully forward in the syringe so that the syringe can be filled by rearward retraction of the plunger. Thus, the reloading operation can involve fully retracting the plunger drive to allow removal and replacement of the syringe, then fully advancing the plunger drive and plunger to expel air from the syringe, and then retracting the plunger drive and plunger to fill the syringe. These lengthy, manual movements of the plunger and drive are time consuming.

The above-referenced patent application describes a front-loading injector in which a syringe can be replaced even though the plunger drive is not fully retracted. This injector substantially reduces the number of plunger drive movements necessary to prepare a syringe for a new injection; after an injection, the syringe can be removed and replaced without moving the drive from its fully-advanced position. (The plunger drive jaw **20** can engage and disengage button **14** regardless of the position of the plunger.) After the syringe is replaced, the drive is retracted, filling the syringe for a new injection. Thus, to ready the injector for a new injection, the plunger drive is manually moved once rather than three times.

Another recent development is the use of pre-filled disposable syringes. A pre-filled syringe also reduces the number of manual plunger drive movements necessary to prepare the injector for a new injection. After an injection, the plunger drive is fully retracted, the used syringe is removed and replaced with the pre-filled syringe, and the injector is ready for a new injection. Thus, again, the plunger drive is manually moved once rather than three times.

To prevent infection, contrast media remaining in a syringe after an injection must be discarded. However, contrast media is relatively expensive. For this reason, when preparing for an injection, an empty syringe is filled with only as much media as will be needed for the next injection. For the same reason, pre-filled syringes are sold in a number of capacities, e.g. ranging from 60 to 125 milliliters, allowing the operator preparing for an injection to select a syringe containing only as much media as is needed for the injection.

A typical pre-filled syringe is illustrated in FIG. **13**. In many respects, the pre-filled syringe is identical to the empty syringe shown in FIG. **1A**. The barrels **10** and plungers **12** have the same size and profile in both syringes (injectors now in use accommodate only a few FDA approved syringe sizes, e.g., a 200 milliliter size and a 125 milliliter size, so all syringes use these sizes). Furthermore, both syringes have a button **14** which is initially located at the end of the barrel **10** (thus, both syringes are compatible with injectors which are designed to grip a button at the end of the syringe). The main difference is that in the pre-filled syringe of FIG. **1B**, the initial location of the plunger **12** is in the middle of the syringe (thus reducing the initial volume of the pre-filled syringe). An extender **16** is attached to button **14** of the plunger, and provides a second button **18** at the end of the syringe which can be gripped by the injector.

SUMMARY OF THE INVENTION

As noted above, at the present state of the art, preparing an injector for an injection requires at least one manual movement of the plunger drive into or out of the syringe barrel, and as many as three such movements. This operation is tedious and inefficient, not only because of the time consumed, but also because the operator must press and hold manual movement switches to produce the movement, and thus is physically tied to the injector and cannot use this time to make other preparations.

In accordance with one embodiment of the present invention, the plunger drive controller has a locked mode in which motion, initially requested by pressing a manual

movement switch, will continue whether or not the operator continues pressing the switch, until the plunger drive reaches its fully-advanced or fully-retracted position. Thus, once the controller has entered the locked mode, the operator may release the manual switch and the desired movement, either advancement or retraction, will continue while the operator makes other preparations for the next injection.

In preferred embodiments, the operator causes the controller to enter the locked mode by pressing the manual movement switch for a predetermined period of time. For safety, the manual movement switch may comprise two buttons which must be simultaneously pressed to produce movement. Movement is initiated by pressing both buttons. While both buttons are held down, the plunger drive controller increases the velocity of movement until the velocity reaches a maximum, at which time the plunger drive controller enters the locked mode. If one button is released before the controller reaches maximum velocity and enters the locked mode, the movement will continue, but at a constant velocity. If the second button is released, the movement will stop. Alternatively, if the controller has reached maximum velocity and entered the locked mode, movement will continue even if both buttons are released; however, if thereafter either button is pressed, movement stops. The controller can provide visual feedback, for example via a light which blinks during motion and lights steadily when the controller is in the locked mode. This light may itself move in synchronism with the plunger drive to provide further feedback on the speed of motion.

As noted, the plunger drive controller is typically manually controlled by means of a switch which, when depressed, causes the plunger drive to move in one of two directions. In accordance with a second aspect of the invention, manual control is improved by providing an adjustment allows the operator to adjust the rate at which the plunger drive moves or accelerates. This permits the operator to customize the operation of the plunger drive controller to enhance individual comfort.

In preferred embodiments, the manual control comprises a wheel which, when rotated, causes the plunger drive to move at a speed which is proportional to the speed of rotation. Alternatively, the manual control may be a forward switch and a reverse switch which cause the plunger drive to move in the indicated direction at a programmable velocity or acceleration.

To operate effectively, the plunger drive controller must determine the location of the plunger **12** relative to the ends of the syringe **10** so that, for example, the controller can determine the amount of contrast media remaining in the syringe. This can be done by a sensor which detects the location of the plunger drive jaw **20**, which is coupled directly to and moves with the plunger **12**. However, a pre-filled syringe may include an extender **16** which changes the relative location of the plunger **12** and the plunger drive jaw **20**, leading to malfunction in the plunger drive controller. In accordance with a third aspect of the invention, malfunction is avoided by storing an offset value representative of the length of the extender **16**, and applying this offset value to the computed drive jaw position.

In preferred embodiments, the offset value may be computed by querying the operator as to the capacity of the syringe and determining therefrom the appropriate offset value. The controller may be configurable so that this query is not made (for example, if the injector will not be used with pre-filled syringes, and therefore the offset value will not change). Alternatively, the offset value may be automatically computed by detecting physical indicia on the syringe or extender which indicate the length of the extender.

These and other aspects will be further illustrated in the following detailed description with reference to the attached drawings, in which:

BRIEF DESCRIPTION OF THE DRAWING

FIG. 1A and 1B are side, partial cut-away views of an empty syringe and a pre-filled syringe, respectively.

FIGS. 2A, 2B and 2C respectively illustrate the console, powerhead, and powerpack of an injector.

FIGS. **3**, **4**, and **5** are electrical and electrical-mechanical block diagrams of the powerpack, console and powerhead, respectively.

FIGS. 6A, 6B, 6C, 6D, 6E and 6F are illustrations of displays produced by the console in operation of the injector.

FIGS. 7A, 7B, 7C, 7D, 7E, 7F and 7G are flow charts illustrating the software operating within the power pack.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

Referring to FIGS. 2A, 2B and 2C, an injection system according to the invention includes three main components, a console **30**, a powerhead **40** and a powerpack **50**.

The console **30** comprises a liquid crystal display **32** of the type used in notebook computers (e.g., a display sold by Sharp Electronics Corp. of 5700 N.W. Pacific Rim Blvd., Camas, Wash. 98607 as part number IL64P62), coupled to an eight key keypad **34** within a housing **36**. As is further elaborated below, display screens presented on display **32** provide injection information and present the user with menus of one or more possible operations, each operation associated with one of the keys on keypad **34**.

The powerhead **40** includes a mount **42** (such as that described in the above-referenced patent application) which accepts a syringe **10** for an injection. The powerhead includes a plunger drive motor (not shown) for moving plunger **12** forward into and rearward out of syringe **10** during an injection in accordance with a preprogrammed sequence, or protocol, selected by the operator by operation of the console **30**.

The location and movement of the plunger drive is indicated by a light emitting diode (LED) which is mounted to the plunger drive and is visible to the operator through a graduated window **44** in the side of the powerhead **40**. As noted below, this LED flashes when the plunger drive is moving, and lights steadily when the plunger drive has been manually locked into forward or reverse motion in the manner described below.

The side of the powerhead **40** includes six pushbuttons: a start/stop button **45**, a forward manual motion button **46**, a reverse manual motion button **47**, and an enable/accelerate button **48**. The three enable/accelerate buttons **48** perform the same function; there are three buttons instead of one to improve operator accessibility.

The start/stop button **45** is used to start an injection protocol selected at the console, or to stop and restart an injection. During an injection, all of the eight buttons on the keypad **34** of the console **30** will perform an identical start and stop function. Furthermore, a remote handswitch (not shown) may be connected to the powerpack **50** (see below) to perform a start and stop function. (For this reason, the start/stop button **45** includes a picture of a handswitch.) To manually move the plunger drive, the operator must simul-

taneously press a motion button **46** or **47** and an enable button **48**. This is a safety feature which reduces the risk of accidental movement of the plunger. If the operator presses the forward button **46** and any of the three enable buttons **48**, the plunger will begin forward motion; conversely, if the operator presses the reverse button **47** and any of the three enable buttons **48**, the plunger will begin reverse motion. Once motion is initiated in either direction, the operator may release one of the buttons; motion will be maintained at a constant velocity in the same direction so long as any one of the five buttons **46**, **47** or **48** is held down. If, instead, after initiating motion in one direction, the operator continues to hold down an enable button **48** and a motion button **46** or **47**, motion will not only be maintained in the same direction, but will be accelerated in this direction until either the operator releases one of the buttons or a maximum velocity is achieved. At any time during the acceleration, the operator may release one of the buttons and hold down the other, and the motion will continue at the same velocity without acceleration. Thereafter, the operator can re-depress the released button, at which time acceleration will begin again.

If the velocity of motion increases to a maximum value, the plunger drive controller (described in more detail below) will enter a locked mode. In this locked mode, movement will continue at the maximum velocity in the same direction even if the operator releases all of the buttons. This frees the operator to perform other tasks when preparing for an injection without being forced to hold manual buttons on the injector until the plunger drive has made the lengthy transition to its fully-advanced or fully-retracted position.

For safety reasons, the locked mode can be terminated readily. If the operator has entered the locked mode and thereafter released all of the buttons, if at any time thereafter any of the buttons is pressed, the plunger drive controller will exit the locked mode and terminate motion.

Two lights **49A** and **49B** mounted on the rear of the powerhead **40** indicate the status of operation of the injector. Light **49A** is an injecting/fault indicator. This light glows while an injection is in process. It will flash if an error is detected. Light **49B** is an enabled indicator. It glows when the injector has been enabled and is ready to perform an injection protocol.

The rear end of the powerhead **40** (opposite mount **42**) includes a jog wheel or switch (not shown in FIG. 2B, see **163**, FIG. **5**) used, in the manner described below, to manually activate motion of the plunger drive.

The powerpack **50** illustrated in FIG. 2C contains electronics which communicate with the console **30** and powerhead **40** to perform the functions described above. The powerpack is connected to the console **30** and powerhead **40** by standard computer communications cables (not shown). Signals carried on these cables are interfaced to circuitry inside of the powerhead, console, and powerpack in a manner described below.

As shown in FIG. **3**, the circuitry in the powerpack includes a central processing unit (CPU) **52** which controls the operations of the powerhead **40** and console **30**. The CPU is preferably a programmable microprocessor such as the MC68332FN microprocessor, manufactured by Motorola, 2110 East Elliot, Tempe, Ariz. 85284. This microprocessor is a member of the 68000 family of microprocessors and features multitasking support; it is designed for use in so called "embedded" environments such as the circuit described herein, and therefore has more than the usual number direct-wired input-output ports.

The CPU connects to an address bus **54** for addressing a number of memory and communications components and a data bus **56** for retrieving and/or sending data from and to these components. Buffers **55** and **57** aid CPU **52** in interfacing to the address and data busses, respectively. Each of the elements connected to the address and data busses are briefly described below.

An erasable programmable read-only memory (EPROM) **58** connected to data bus **56** contains the program software which operates the CPU **52**. The EPROM contains an operating system, which performs low-level management of the CPU and its communications with other circuits, and a custom program for controlling the console and powerhead to perform injection protocols. In one embodiment, the operating system software is the USX68K operating system, a multi-tasking operating system for 68000 series microprocessors sold by U.S. Software of 14215 N.W. Science Park Drive, Portland, Oreg., 97229, and the custom program is written in the "C" programming language. This custom program is described below, and a copy of the "C" language source code for the custom program appears in the appendix to this application.

A second EPROM **60** connected to data bus **56** contains language information used by the program software in EPROM **56** when generating displays for presentation on the display **32** (FIG. **2A**). As will be further elaborated below, the display screens presented on the display **32** include textual descriptions of actions being taken by the injector, and menu selections which the operator can select. The textual portions of these display elements are stored in the language EPROM **56**, from which they are retrieved and inserted into a template as CPU **52** is producing a display screen. Preferably, the language EPROM contains multiple versions of each textual insert, representing different languages, so that the operator can, through menu choices entered at the console keypad **34**, choose a preferred language in which to generate screen displays. An exemplary set of languages suitable for the North American and European markets would be English, German, French and Spanish.

A third, electrically erasable and programmable read only memory (EEPROM) **62** is attached to the data bus. EEPROM **62** stores data in a non-volatile manner (so that it will not be lost when the power is turned off). Among other things, EEPROM **62** stores preprogrammed injection protocols. These protocols are created and stored by the user as desired (details are reviewed with reference to FIG. **6A**, below). In addition, EEPROM **62** stores calibration information, used by CPU **52** in interpreting fluid pressure and plunger position information which it receives while performing an injection. Further, EEPROM **62** stores information on the most recently completed injection, such as the injection time and volume, so that this information may be retrieved by the operator. EEPROM **62** also stores operator preference data entered by the operator into the console (see FIG. **6E**, below). This includes the preferred display language, time, and date formats. Moreover, EEPROM **62** stores operating parameters such as a programmable pressure limit, and a flag (used in the manner described below) indicating whether the injector will be used with partially pre-filled syringes of the kind illustrated in FIG. **1B**. Finally, EEPROM **62** stores the registered name and/or number of the machine owner, to facilitate service and on-line customer support.

Data bus **56** is also connected to a random access memory (RAM) **64** which is used by the operating system to store a stack of register values generated during CPU operations and machine state information corresponding to currently inactive processes running on the CPU. The application

software uses the remaining space in RAM **64** (as managed and allocated by the operating system) to store variables computed and manipulated during operation of the injector.

Most communications between CPU **52** and the powerhead **40** and console **30** flow through one of two universal asynchronous receiver/transmitters (UARTs) **66**, **68** which are connected to the data bus. A UART is a communications circuit, generally available in integrated circuit form, which collects and buffers incoming and outgoing information to enable asynchronous communications between processors or computing systems over a data link. A suitable UART is the MC68681, sold by Motorola. The first UART **66** is responsible for communications with the powerhead circuitry (see FIG. **5**, below), which pass through an interface **70** and a communications cable **71** connected to the powerhead. (However, pulses from the optical encoder **166** on the powerhead (FIG. **5**, below) travel directly from interface **70** along line **71** to an interrupt input on the CPU **52**.) UART **66** also handles communications with an auxiliary interface **72**, which can be coupled through a communications cable **73** to a printer to allow CPU **52** to print records of an injection. Alternatively, interface **72** (or another, similar interface) can be used to attach CPU **52** to a remote computer or other external device to allow remote monitoring and/or control of the injector.

The second UART **68** is responsible for communication with the console **30** (FIG. **2A**). Two consoles **30** can be connected to the powerpack via cables **75**, **76**.

Cables **75** and **76** carry data representing keystrokes and screen activity between the powerpack **50** and console **30**. This data is encoded in a communications protocol and transmitted in accordance with the RS422 standard. The encoded data is carried via lines **75** and **76** to interface **74** which encodes and decodes transmissions for a second UART **68**. UART **68** routes keystrokes received by either console via interface **74** to CPU **52** via the data bus **56**, and further routes display information produced by CPU **52** to interface **74** for transmission to the consoles via lines **75A** and **76A**.

Cables **75** and **76** also include, on separate conductors, lines **75B** and **76B**, which carry logical signals corresponding to key **38** (FIG. **2A**) of each console keyboard. As elaborated below, the software driving the console displays is written so that key **38** is the most frequently used key—depending on the screen being displayed, key **38** will function as an "Exit" key to depart the screen, an "Enter" key to accept a value or selection and depart the screen, or a "Disable" or "Cancel" key to terminate an operation. (Exemplary screens are discussed below with reference to FIGS. **6A–6F**.) Because key **38** is the most frequently used key, and because key **38** is used for time-sensitive input such as a cancel command, key **38** is connected to the CPU **52** differently than the other keys. Key **38** is connected directly to the CPU **52** via an interrupt line **79**; when a keystroke is detected, a non-maskable interrupt interface (NMI) **78** (which essentially constitutes a RS422 transmitter and receiver which converts the signal on lines **75B** and **76B** to a clean logic signal on line **79**) sets an interrupt on line **79**, which is immediately detected and subsequently serviced by CPU **52**.

A similar interface is used for the remote handswitch. The cable **81** leading from the handswitch connects to the handswitch interface circuit **80** which among other things, electrically isolates the handswitch from the powerpack ground, and "de-bounces" the handswitch (eliminates electrical noise created when the switch is pressed or released) so as to provide a clean logic signal indicating whether the handswitch button is being pressed or is released. This logic signal is connected, via line **82**, to a time processor unit (TPU) port on CPU **52**. CPU **52** reads the logic signal at this TPU port and responds appropriately according to the software in EPROM **58**.

The last component on the CPU data bus **56** is an analog to digital converter (AID) **84**. This converter is used to generate a digital signal, readable through data bus **56**, which corresponds to an analog signal received on line **85**. A suitable A/D converter is the LT1094, sold by Linear Technology of 1630 McCarthy Blvd., Milpitas, Calif. 95035. A/D converter **84** is used by the motor servo control circuitry described below. The CPU has two additional interfaces to the motor servo control circuitry: an interface on line **87** to a digital to analog converter (D/A) **86** (which generates an analog signal on line **88** corresponding to a digital signal received on line **87**, for example the AD7245, sold by Analog Devices of One Technology Way, P.O. Box 9106, Norwood, Mass. 02062), and a second interface on line **90** to pressure limit control circuit **92**. These interfaces (lines **87** and **90**) connect to synchronous peripheral interface (SPI) channels on the microprocessor, and are controlled in accordance with the software in EPROM **58**.

The D/A **86**, A/D **84**, servo control **94**, pressure limit control **92**, and pressure sense **96** circuits collectively form a motor servo control circuit which controls the operation of the motor **98** which drives the syringe plunger into and out of the syringe. (Motor **98** is shown for clarity, but it should be understood that motor **98** is physically located in the powerhead **40** (FIG. **23**, **5**); lines **91** and **93** connect to the motor through several conductors of the computer interface cable connecting the powerhead **40** and the powerpack.)

Servo control circuit **94** responds to an analog voltage produced by D/A **86** on line **88** and produces a corresponding voltage between lines **99** and **100**. The voltage on lines **99** and **100** is transformed by transformer **102** to a level sufficient to drive motor **98** via lines **91** and **93**. Servo control circuit **94** contains a flyback transformer circuit which produces an output voltage related to the duty cycle of a switching FET. This duty cycle is produced by a UC3525 pulse width modulation (PWM) circuit—an integrated circuit which produces a 100 kHz digital output signal having a duty cycle which varies from 0% to 50% in response to an analog input voltage on line **88**. A suitable PWM circuit is the UC3525, sold by Unitrode of 7 Continental Boulevard, Merrimack, N.H. 03054. Thus, CPU **52** controls the speed and power output of motor **98** by writing a digital word representing a desired output voltage to D/A **86** via lines **87**; this digital word is then converted to an analog signal, and the analog signal is converted to a pulse width modulated control signal in the servo control, resulting in the desired output voltage at the motor.

Pressure sense circuit **96** includes a current sense circuit of which detects the current flow through line **93** (i.e., through the motor) and produces analog signals on lines **104** and **85** proportional to the detected current. In essence, this current sense circuit comprises a low-value, high power rating resistor in series with line **93** which attached to the motor **98**. A differential voltage amplifier (based on a low-noise, high common mode rejection op-amp) senses the voltage across the resistor and converts it to an analog voltage on lines **85** and **104**. The current flow through the motor is proportional to the force exerted by the motor and therefore to the injection pressure. Thus, the analog signals produced by pressure sense circuit **96** can be used to derive the injection pressure.

Pressure limit control circuit **92** uses the analog signal on line **104** to perform a hardware pressure control function. Pressure limit control circuit **92** contains a commercially available digital potentiometer, used to produce an analog comparison voltage. A suitable potentiometer is the DS1267, sold by Dallas Semiconductor of 4350 Beltwood Parkway South, Dallas, Tex. 75244. CPU **52** (via lines **90**) programs this potentiometer to produce a comparison voltage corresponding to the maximum allowable pressure. Pressure limit control circuit **92** includes a comparator which compares the analog signal on line **104** produced by pressure sense circuit **96** to the comparison voltage. If the pressure exceeds the maximum allowable pressure (indicating a failure in the CPU **52**), a digital signal is transmitted on line **105** to servo control circuit **94**, which in response ignores the analog signal on line **88**, and instead reduces the voltage on lines **99** and **100** to halt the motor. Thus, once the CPU **52** has programmed pressure limit control circuit **92** with the correct maximum pressure, the injector will not exceed this pressure even if the CPU **52** fails.

Under normal conditions, this hardware pressure limit will not be activated, because CPU **52** continuously obtains feedback on the performance of the motor and the pressure produced and controls the motor through D/A **86** to achieve the desired injection protocol. CPU **52** obtains feedback on an ongoing injection from three sources: (1) feedback on the injection pressure is obtained from A/D **84**, which produces a digital word on bus **56** corresponding to the analog voltage on line **85** produced by pressure sense circuit **96**; (2) feedback on the motor speed is obtained from an optical encoder **166** physically coupled to the motor inside of the powerhead **40** (elaborated with reference to FIG. **5**, below); and (3) feedback on the position of the plunger inside of the syringe is obtained from a linear potentiometer **168** physically coupled to the plunger (see FIG. **5**, below). Using this information, CPU **52** carefully controls the injection pressure, volume and speed according to a preprogrammed protocol under control of software in EPROM **58**.

Power for the powerpack, powerhead, and console display is supplied by the AC power lines **107** and **108**. The AC line voltage is conditioned by a conventional power supply circuit **106** which includes a transformer which can be adjusted for use with non-United States line voltages, and a voltage sense circuit for selecting the appropriate transformer based on the detected line voltage. The power may be turned off by unplugging the injector, or preferably by a toggle switch which opens and closes a solid-state relay in remote on/off circuit **110**.

Referring to FIG. **4**, the console circuitry is also built around a general purpose CPU **120**. A suitable microprocessor is the MC68332FN. The address bus **122** and data bus **124** connected to CPU **120** connect to a number of supporting circuits. Program ROM **126** contains the software which directs CPU **120**. (This software is written in assembly language, and is included in the attached appendix). Font ROM **128** includes font information retrieved by CPU **120** in producing fonts for text generated on the display screen. These fonts include foreign-language characters where necessary to support foreign language text. RAN **130** is used by microprocessor in performing display and retrieval operations. Battery-backed RAM **132** stores the current time of day, so that the powerpack may make a date and time-stamped record of an injection.

The primary function of the console circuitry is to generate screens on the display **32**, and to receive keystrokes from the eight-key keypad **34** (FIG. **2A**) and relay the keystrokes to the powerpack. Displays are generated by a display controller **134**, such as the F82C455 VGA contrdler sold by Chips & Technologies of 3050 Zanker Road, San Jose, Calif. 95134. This VGA controller interacts with CPU **120** via an address buffer **136** and data buffer **138**, and stores screen information in a dynamic random access memory (DRAM) **140**. Information is sent over lines **142** to the display **32**.

Keystrokes from the keypad are received by keyboard interface circuit **144** which "debounces" the keystrokes, producing clean logic signals on lines **146**. These logic signals are fed back to CPU **120** so that it may confirm keystrokes by producing an audible tone through speaker control circuit **150**. Speaker control circuit also generates unique audible signals to indicate other operations, such as the initiation of an injection, or to notify the operator that scanning should begin. A suitable controller is the MC3487, sold by Motorola.

CPU **120** communicates with the powerpack via an RS422 interface circuit **148** which sends and receives digital signals over lines **75** and **76**. Interface circuit **148** also receives and forwards keystrokes directly from keyboard interface **144**. The eight keys on the console form a single, eight bit byte of information (where each bit indicates whether the key is pressed or released). This byte is coupled directly to CPU **120** via a "245" type logical buffer.

+28 Volt DC power is received from the power supplies in the powerpack via lines **152**. A power supply circuit **154** regulates this +28 Volt DC power line into a collection of supply voltages, as needed by the various circuitry in the console. Furthermore, a power inverter circuit converts +12 Volt DC power produced by the power supply circuit **154** into low-current 600 Volt AC power supplies for energizing the liquid crystal display.

Referring to FIG. **5**, the powerhead also includes a circuit board **160** including microprocessor to perform communications with the powerpack **50** (FIG. **2C**). A suitable microprocessor is the 68HC11E2, sold by Motorola, which is a low-cost, minimal functionality microprocessor in the 68000 family. The circuit board receives and forwards keystrokes from the buttons on the keyboard **162** (described above), and electrical pulses indicating movements from the manual knob **163** mounted on the rear of the powerhead. A suitable manual knob is the model 600 thumbwheel, sold by Clarostat of 1 Washington Street, Dover, N.H. 03820. The circuit board also lights and extinguishes the injecting/fault indicator light **49A** and the enabled indicator light **49B**.

The motor **98** is coupled to a gear box which translates rotary motion of the motor to linear translation of the plunger. One suitable motor is the CYMS A2774-2 motor, sold by Barber-Colman, P.O. Box 7040, Rockford, Ill. 61125. The rotation of the motor is detected by optical encoder **166** (encoder **166** essentially comprises a pinwheel which rotates between a light source and a light detector to produce electrical pulses, for example the HEDS-9100 encoder, sold by Hewlett-Packard of 3003 Scott Boulevard, Santa Clara, Calif. 95054). Encoder **166** sends electrical pulses to circuit board **160**, which relays them to powerpack **50**, allowing CPU **52** on the powerpack to monitor movement of the motor.

The position of the plunger is detected by a linear potentiometer **168**, for example the LCPL200, sold by ETI Systems of 215 Via Del Norte, Oceanside, Calif. 92054. The wiper **169** of potentiometer **168** is mechanically coupled to and moves with the plunger **12**. A DC voltage drop is placed across the potentiometer terminals **170** and **171**, and as a result, an analog voltage representative of the location of the

plunger and wiper **169** is produced at the wiper **169**. An A/D converter on circuit board **160** converts this analog voltage to a digital signal which circuit board **160** forwards to the powerpack **50**.

Circuit board **160** also detects the output of two Hall effect sensors **172** and **174**. The powerhead has a removable face plate **42** (FIG. 2B). There are currently two different face plates having differently-sized apertures for accepting differently-sized syringes. Thus, although the face plate need not be removed to replace the syringe, it may be removed to use a different syringe size. Sensor **172** detects whether face plate **42** is open, and if so circuit board **160** sends a message to powerpack **50** which prevents any further injection procedures until the face plate is closed. Sensor **174** detects the size of the face plate in use. Currently, only one of the two face plates includes a magnet which triggers sensor **174**; thus, circuit board can determine which face plate has been installed by determining whether sensor **174** has been triggered. This information is also forwarded to CPU **52** in the powerpack so that CPU **52** may compensate for the different syringe sizes when controlling motor **98** (as described below).

At the direction of CPU **52**, circuit board **160** also controls heater blanket **176**, which heats the contrast fluid in the syringe. Furthermore, circuit board **160** controls movement indicator board **178**. Movement indicator board **178** is mechanically coupled to the plunger **12** and includes two light emitting diodes LEDs **179** which are visible through window **44** on the powerhead (FIG. 2B). LEDs **179** provide the operator with feedback on the position of the plunger, by correlating the position of the diodes with the graduated scale on window **41**. The two sides of the window **41** contain different graduated scales: one calibrated for large syringes and one for small syringes. Depending on the syringe size detected by sensor **174**, the LED next to the appropriate graduated scale is illuminated. Furthermore, as discussed in more detail below, when the plunger is moving, CPU **52** directs circuit board **160** to flash the LED. Also, when the CPU **52** enters its "locked mode" (discussed above), CPU **52** directs circuit board **160** to steadily light the LED. Thus, LEDs **179** provide operator feedback on the plunger position, direction of motion, and the "locked mode".

Referring to FIGS. 6A–6F, an injection protocol will be described from the operator's perspective. The main operating screen is illustrated in FIG. 6A. Box **200**, which is associated with an iconic representation **201** of the powerhead, identifies the current volume of contrast media in the syringe. Box **202**, which is associated with an iconic representation **203** of the syringe, identifies the total volume which has been dispensed during the currently selected protocol. Box **204** identifies the pressure limit pre-selected by the operator for the procedure, and box **206** identifies a scan delay (in seconds), which is the delay from the time the operator initiates an injection (either with the handswitch, a key on the console or a button on the powerhead) until the x ray or magnetic scan of the subject should begin (at the end of this delay, CPU **120** produces a tone indicating to the operator that scanning should begin; alternatively, scanning could be automatically initiated by a suitable electrical connection between the scanner and injector). In the illustrated situation, the syringe contains 180 ml of fluid, 30 ml of which will be used by the currently selected protocol, the pressure limit is 200 psi and there is no scan delay.

In the display illustrated in FIG. 6A, the upper regions of the screen display stored injection protocols. Region **208** identifies protocols which the operator may select, and region **210** gives details of the currently selected protocol. As shown in region **210**, a protocol comprises a number of phases; during each phase the injector produces a pre-programmed flow rate to output a pre-programmed total fluid volume. The illustrated protocol "SERIO VASCUL" has only one phase; however, other protocols which can be selected by the operator have multiple phases. In region **208**, protocols are identified by name and by number of phases; thus, as illustrated, the "LIVER" protocol has 2 phases and the "ABDOMEN PI" protocol has 3 phases.

The user can select protocols, enable an injection, and otherwise navigate through display screens by pressing the buttons on the keypad **34** next to the display. Region **212** of the display is dedicated to identifying the functions available from the buttons on the keypad **34**. Thus, in this display illustrated in FIG. 6A, the user may select the previous or next protocol in the list in region **208** by pressing the buttons next to the words "PREVIOUS PROTOCOL" and "NEXT PROTOCOL", respectively, on the display. The user may also change and store the flow, volume and inject delay values for the current protocol by pressing the button next to "CHANGE VALUES"; doing so will alter the function of the keypad and region **212** of the display, so that the operator may select a value, increment and decrement the value, select characters to form or edit a protocol name, and then return to the display shown in FIG. 6A. From FIG. 6A, the operator may also enter a control panel display (see FIG. 6E, below) to adjust operating parameters and other data. Also, the operator may enter a protocol manager in which the operator may rename or delete protocols, and may determine the order of the protocol list shown in region **208**. Finally, the user may also enable an injection from the display illustrated in FIG. 6A by pressing the button next to "ENABLE".

As shown in FIG. 6B, when the user enables an injection, as a safety measure, the injector first presents a text box **214** which asks the operator whether all of the air has been evacuated from the syringe. Region **212** of the display contains only the words "YES" and "NO", indicating that the operator must answer the question as either yes or no. If the button next to "NO" is pressed, the injection will be cancelled. If the answer is "YES", the injector will proceed to an enabled state, illustrated in FIG. 6C. Here, region **208** of the display indicates the expected duration, and region **212** includes the word "START", "AUTO ENABLE" and "EXIT". If the operator presses the button next to "EXIT", the injector will return to the state illustrated by FIG. 6A. If the operator presses the button next to "AUTO ENABLE", the injector will toggle into and out of the auto-enabled mode, as confirmed by a briefly-displayed box in the center of the screen. If the operator presses the button next to "START" the injection will begin and the injector will move to the state illustrated by FIG. 6D.

While an injection is proceeding, the display shown in FIG. 6D is displayed. In this display, region **208** indicates the total injection time and the volume (in ml) delivered to the patient. Region **212** shows the word "STOP" next to each of the buttons on the keypad **34**, indicating that the operator may stop the injection by pressing any of the buttons (or by pressing the start/stop button **45** on the powerhead, or by pressing the handswitch). In addition, in box **200**, the total volume of fluid in the syringe counts down as fluid in injected into the subject.

After the injection protocol has completed, the injector will return either to the state illustrated by FIG. 6A or to the state illustrated by FIG. 6C. If the operator put the injector in the auto-enable mode by pressing "AUTO ENABLE" at FIG. 6C, the injector will return to the state illustrated by

FIG. 6C. However, if the operator did not put the injector into the auto-enable mode, the injector will return to the state illustrated by FIG. 6A. Thus, by placing the injector in auto-enable mode, the operator can more easily repeat an injection protocol; this can be useful where, for example, the contrast media dissipates relatively rapidly, and multiple images will be taken on the same area of the subject. By using "AUTO ENABLE", the operator may replenish the contrast media just before each image by pressing a single key (or the handswitch), without re-enabling the injector.

As noted above, injection operators may wish to use prefilled syringes for injections. However, prefilled syringes often include extenders which reduce the filled volume of the syringe (syringes of this type are known as "partial pre-filled" syringes). The injector described herein includes a feature for compensating for the reduced volume of partial pre-filled syringes, described below.

As noted above, to set up the injector, the operator may enter the "Control Panel", illustrated in FIG. 6E. In the control panel, the display identifies the current operational settings of the injector. Thus, the control panel includes a box **220** which identifies the current pressure limit, a box **222** which identifies the current language (as noted above, the operator may choose a language for the textual portions of the display), boxes **226** and **228** which identify the current time and date, and a box **230** which identifies the owners registration name and/or number. This information is entered using the keypad and region **212** of the display in the manner discussed above.

An additional box **232** on the "Control Panel" display is used to indicate whether partial pre-filled syringes will be used with the injector. Box **232** will include the word "YES" or "No", as selected by the operator (as shown in FIG. 6E, when the user attempts to modify this box, region **212** of the display provides a menu with the choices "YES" or "NO").

If the operator has modified box **232** to indicate that partial pre-filled may be used (i.e., box **232** has a "YES"), then the enable procedure described above is modified slightly. If partial pre-filleds may be used, after the operator enables an injection by pressing "ENABLE" at the display of FIG. 6A, the injector presents the screen illustrated in FIG. 6F, in which the operator must identify the pre-filled syringe size by pressing a button next to "50 ml", "65 ml", "75 ml", "100 ml", or "125 ml". Once the operator has identified the prefilled syringe size, the injector will continue to the display illustrated in FIG. 6B. CPU **52** (FIG. 3) will then compensate for the extender in the syringe, in the manner described below with reference to FIG. 7B.

Referring to FIG. 7A, the program operating in CPU **52** is initiated **240** when the power is turned on. The program first initializes **242** the hardware and software attached in powerpack **50**, powerhead **40** and display **30**. Then, CPU **52** performs **244** diagnostics to ensure that the injector is operating properly; essentially, this involves sending test data to various hardware elements and verifying that the appropriate responses are received.

After these diagnostics have passed, CPU **52** initiates a number of "threads", or parallel processes; thereafter, these processes are time-multiplexed on CPU **52** under control of the above-described USX68K operating system. These threads communicate with the operating system and with each other by "messages" or semaphores—essentially, inter-process communications are placed in a globally accessible area, managed by the operating system, where they can be later retrieved by other threads. The operating system allocates processing time to the threads. Much of the time, a thread will be "inactive", i.e., it will not have any pending operations to perform. The threads are generally written so that, if the thread is inactive, it will notify the operating system of this fact ("return time" to the operating system) so that the operating system can reallocate processing time to another thread.

The operating system allocates processing time to threads in a prioritized, round-robin fashion. Thus, the operating system will provide processing time to each thread generally in turn; if an active, low-priority thread uses more than a maximum amount of processing time, the operating system will interrupt the thread, and provide other, higher priority threads with an opportunity to use processing time. However, a high-priority thread will not be interrupted by lower priority threads, regardless of whether the high-priority thread uses more than the maximum amount of processing time. Under normal operation, most of the threads are inactive, and there is no conflict between threads for processing time; however, in those occasions where there is a conflict, this prioritized system allows the most important threads to continue uninterrupted where necessary. It should be noted, however, that even the highest priority thread (servo thread **254**) occasionally returns time to the operating system (at those moments where an interruption can be tolerated), so that other threads are able to continue their operations even while the highest priority thread is active.

The threads operating in the CPU **52** generally fall into two categories: "communicating" threads which send information into and out of the powerpack **50**, and "operating" threads which generate or process the information sent or received by the powerpack. There are two operating threads: state machine thread **246** and servo thread **254**.

State machine thread **246** directs the console **30** to produce screen displays of the type shown in FIGS. 6A–6E, and also processes button presses by the user. Thread **246** is essentially a state machine, where each "state" corresponds to a display screen, and each operator keystroke produces a state transition. The software in program EPROM **58** (FIG. 3) essentially defines a state transition diagram, identifying specific states, displays associated with those states, and, for each state, the keystrokes or other activity which will cause a transition to another state.

As shown in FIG. 7B, when initiated, thread **246** looks **270** for a message, for example a message from a communications thread indicating that console button was pressed, or a message from the servo thread indicating that the display should be updated to reflect recent injection activity. If no message has been received, the thread returns **272** time to the operating system. However, if a message has been received, the thread uses the software in program EPROM **58** to identify and transition **274** to the new state associated with the received keystroke or activity. In some cases, e.g. where the operator has pressed an invalid button, the new state will be the same as the old state; in other cases, the new state will be a different state. If the new state is a different state, the state machine thread sends messages to the appropriate communication thread to modify **276** the screen to reflect the new state. In addition, the state machine thread may send 278 messages to the servo thread, e.g. to notify the servo thread that the operator has pressed a button which starts a protocol. When this is completed, the state machine returns 280 to the operating system.

When a start message is sent to the servo thread, the thread sending the message initiates one or more global variables to indicate the kind of movement requested. Eight

global variables (variables managed by the operating system and accessible by all threads), organized into four pairs, are used for this purpose. Each pair of variables identifies a desired new position for the plunger and a speed at which the plunger should move to that position. Four protocol phases can be described by the four variable pairs, and thus may be executed in one message to the servo thread. Thus, when the state machine thread sends **278** a message to the servo thread, it computes one or more desired ending positions and speeds from the selected protocol, and places the computed values into global variables.

Referring to FIG. **7**C, when initiated by the operating system, the servo thread **254** first checks **282** for a message telling the servo to start motion of the plunger. If no message is received, the servo thread returns **284** time to the operating system. If, however, a start message has been received, the servo thread starts **286** the motor to move to the desired position indicated by a global variable at the desired speed indicated by a global variable. At this point, the servo thread enters a loop; during each iteration the loop checks **288** if the plunger has arrived at the desired position (the plunger position is determined by the powerhead receive thread **260** as illustrated in FIG. **7**E, below), and if so, the loop terminates and the servo thread stops **290** the motor and returns. However, if the plunger has not arrived at the desired position, the servo thread checks **292** if the speed of the motor is correct (the motor speed is measured by an interrupt routine illustrated in FIG. **7**D, below). If the motor speed is incorrect, it is corrected **294** by adjusting the motor voltage. Once these steps are completed, the servo thread allows **296** the operating system three time slices (about 21 milliseconds) to operate other processes, after which it returns to step **288** to close the loop.

Referring to FIG. **7**D, as noted above, the motor speed is measured by an interrupt routine. When a pulse is detected from the optical encoder **166** (FIG. **5**) attached to the motor **98**, the processor in the powerhead circuit board **160** causes an interrupt to travel on line **71** to CPU **52**. When this interrupt is received **300**, the interrupt routine computes **302** the time elapsed from the previous count interrupt, and from this elapsed time computes **304** the plunger speed. This speed value is stored **306** in a global variable (where it can be accessed by the servo routine), and the interrupt is done **308**.

Referring to FIG. **7**E, the powerhead receive thread **260** is responsible for receiving messages from the powerhead and performing a number of tasks in response, including relaying manual movements of the plunger to the servo thread and (as noted above) relaying position measurements to the servo thread during movement of the plunger.

When the operating system initiates **260** the powerhead thread, the thread first checks **310** for any messages; if none have been received, the thread returns **312** time to the operating system. However, if the thread has received a message, it determines **312** what the message is and acts appropriately (this determination is illustrated for clarity as a multi-way branch, but in the code in the fiche appendix it is implemented as a series of individual tests performed on in sequence). The message may contain an error message **314**, a manual knob movement **316**, a linear potentiometer reading **318** (which are periodically generated by the powerhead), a fill button reading **320** (which is periodically generated by the powerhead), a start/stop button press **322**, or several others (multiple messages may be received at one time).

As shown in FIG. **7**E, if the message contains a linear potentiometer reading **318**, the reading is converted **324** into an equivalent volume (using calibration readings stored in EEPROM **62**). Then, an offset value (which compensates for the presence of the extender in a partial pre-filled syringe), is subtracted **326** from the computed volume, and the result is stored in a global variable, where it can be later accessed by the servo thread at step **288** (FIG. **7**C). The offset value used in step **326** is generated when the user identifies the partial pre-filled size in response to the display shown in FIG. **6**F; if partial pre-filled syringes are not used, the offset is set to a constant zero value. Once the adjusted volume is stored, the powerhead thread returns **328** time to the operating system.

As shown in FIG. **7**F, when a fill button reading is received (i.e., the received message indicates the state of buttons **46**, **47** and **48** on the keyboard **162** of the powerhead), the powerhead thread first determines **330** which button, or buttons, are pressed.

If a "fast" button **48** and the forward button **46** or reverse button **47** are pressed **332**, the thread first determines **334** whether the motor is at its maximum, latching speed (by reading the global variable indicating the motor speed, as produced by the interrupt routine illustrated in FIG. **7**D). If not, the thread increases **336** the motor speed in the indicated direction—by increasing the value of the global variable identifying the desired speed, setting the global variable identifying the desired location to identify the end of the syringe (and sending a start servo message to the servo thread if the motor is not already running)—and returns **338** time to the operating system. If, however, the motor has reached its latching speed, then the thread determines **340** if buttons were pressed the last time a fill button reading was processed. If so, then the operator has accelerated the motor to its maximum speed and is continuing to hold down the buttons. In this situation, the motor should continue running at its maximum speed; therefore, the thread simply returns **338** time to the operating system. If, however, buttons were not pressed last time, then the operator latched the motor at maximum speed, released the buttons, and some time later pressed a button in an attempt to stop the motor. Thus, in this situation, the thread stops **342** the motor (by setting the global variable indicating the desired speed to zero), and returns **338** time to the operating system.

If the operator is pressing **344** the forward or reverse buttons alone, or any other combination of buttons, the thread first determines **346** if the motor is running (by checking the value of the global variable indicating the motor speed). If the motor not running, then a single keystroke will not start it running, so the thread simply returns **338** to the operating system. If, however, the motor is running, then the thread determines **348** if buttons were pressed the last time a fill button reading was processed. If buttons were pressed last time, then the operator is merely trying to keep the motor running at its current speed by holding a button down; therefore, in this situation, the thread simply returns **338** to the operating system, allowing the motor to continue running. If, however, buttons were not pressed last time, then the operator latched the motor at maximum speed, released the buttons, and some time later pressed a button in an attempt to stop the motor. Thus, in this situation, the thread stops **342** the motor (by setting the global variable indicating the desired speed to zero), and returns **338** time to the operating system.

If no buttons are pressed **352**, the thread simply determines **354** if the motor is at its latching speed. If not, the thread stops **356** the motor and returns time to the operating system. Otherwise, the thread returns **338** directly, allowing the motor to continue running at the latching speed.

Referring to FIG. 7G, manual motion can also be created by turning the manual knob **163** (FIG. **5**) mounted on the rear of the powerhead. As noted above, the powerhead CPU **160** regularly reports movements of the manual knob to the powerpack CPU **52**. This report identifies the direction of rotation and the number of electrical pulses received from the knob since the last report (more pulses indicating greater speed of rotation). When a manual knob message is received **316**, the powerhead receive thread first computes **340** a desired plunger speed from the number of pulses identified in the message, and computes **342** a desired end position from the number of pulses and the direction of rotation of the knob. These are then stored **344** in global variables accessible to the servo thread as described above. If the motor is not already running, the powerhead receive thread also sends a servo start message to the servo thread. Then the thread returns **346** time to the operating system.

The invention has been described with reference to a specific embodiment. However, it will now be understood that various modifications and alterations can be made to this specific embodiment without departing from the inventive concepts embodied therein. For example, the manual motion knob **163** may be replaced by any other control which allows velocity and direction control, for example by a button or knob which can be rotated or rocked to multiple positions corresponding to various velocities and directions of motions, or a set of buttons or knobs which allow the operator to separately select a desired velocity with one button or knob and a desired direction with another button or knob. Therefore, this specific embodiment is to be interpreted as exemplary and not limiting, with the scope of protection being determined solely from the following claims.

What is claimed is:

1. An injector and syringe, comprising:

a syringe having a plunger, a nozzle located in the front of said syringe, and physical indicia related to the distance of the plunger from an end of said syringe when said syringe is initially installed on said injector,

a motor in the injector which advances and retracts the plunger located within the syringe toward and away from the nozzle of the syringe to inject fluid into or out of an animal subject, and

a controller in the injector adapted for use with syringe assemblies which have differing capacities, comprising:

a detector located proximate to the syringe when installed on said injector for detecting the physical indicia on said syringe, and generating an electrical signal representative of said physical indicia, and

a control circuit which causes said motor to move and tracks the location of said motor while moving said motor, wherein said control circuit computes the relative location of said plunger within said syringe, using said electrical signal and the tracked location of said motor.

2. The injector of claim **1** wherein said control circuit ceases motion of said motor and plunger when a location of said plunger computed by said control circuit indicates that said plunger has arrived at an end of said syringe.

3. The injector of claim **1** wherein said electrical signal represents the length of an extender which is attached to said plunger within said syringe.

4. A method of controlling an injector of the type having a motor which advances and retracts a plunger located within a syringe toward and away from a nozzle located at an end of the syringe to inject fluid into or out of an animal subject, adapted for use with syringe assemblies which have differing capacities, comprising:

detecting a physical indicia on a syringe installed on said injector, said indicia being related to the distance of the plunger from an end of said syringe when said syringe is initially installed on said injector, and generating an electrical signal representative of said physical indicia,

causing said motor to move,

tracking the location of said motor while moving said motor, and

computing the relative location of said plunger within said syringe, using said electrical signal and the tracked location of said motor.

5. The method of claim **4** further comprising:

ceasing motion of said plunger when a computed location of said plunger indicates that said plunger has arrived at an end of said syringe.

6. The method of claim **4** wherein said electrical signal represents the length of an extender which is attached to said plunger.

7. An injector and syringe, comprising

a syringe having a plunger, a nozzle located in the front of said syringe, and physical indicia related to the amount of fluid in the syringe,

a motor in the injector which advances and retracts the plunger located within the syringe toward and away from the nozzle of the syringe to inject fluid into or out of an animal subject, and

a controller in the injector adapted for use with syringe assemblies which have differing capacities, comprising:

a detector located proximate to the syringe when installed on said injector for detecting the physical indicia on said syringe, and generating an electrical signal representative of said physical indicia, and a control circuit which causes said motor to move and tracks the location of said motor while moving said motor, wherein said control circuit computes the amount of fluid in said syringe using said electrical signal and the tracked location of said motor.

8. The injector of claim **7** wherein said control circuit ceases motion of said motor and plunger when a location of said plunger computed by said control circuit indicates that said syringe is empty.

9. The injector of claim **7** wherein said electrical signal represents the length of an extender which is attached to said plunger within said syringe.

10. A method of controlling an injector of the type having a motor which advances and retracts a plunger located within a syringe toward and away from a nozzle located at an end of the syringe to inject fluid into or out of an animal subject, adapted for use with syringe assemblies which have differing capacities, comprising:

detecting a physical indicia on a syringe installed on said injector, said indicia being related to amount of fluid in said syringe, and generating an electrical signal representative of said physical indicia,

causing said motor to move,

tracking the location of said motor while moving said motor, and

computing the amount of fluid in said syringe using said electrical signal and the tracked location of said motor.

11. The method of claim **10** further comprising:

ceasing motion of said plunger when a computed location of said plunger indicates that said syringe is empty.

12. The method of claim 10 wherein said electrical signal represents the length of an extender which is attached to said plunger.

13. An injector and syringe, comprising

a syringe having a plunger, a nozzle located in the front of said syringe, and physical indicia related to the end of travel position of an injector ram coupled to the plunger when the syringe is coupled to an injector,

a motor in the injector which advances and retracts a ram coupled to the plunger located within the syringe toward and away from the nozzle of the syringe to inject fluid into or out of an animal subject, and

a controller in the injector adapted for use with syringe assemblies which have differing capacities, comprising:

a detector located proximate to the syringe when installed on said injector for detecting the physical indicia on said syringe, and generating an electrical signal representative of said physical indicia, and

a control circuit which causes said motor to move and tracks the location of said motor while moving said motor, wherein said control circuit determines that the ram hag arrived at its end of travel position, using said electrical signal and the tracked location of said motor.

14. The injector of claim 13 wherein said control circuit ceases motion of said motor and plunger when the ram has reached its end of travel position.

15. The injector of claim 13 wherein said electrical signal represents the length of an extender which is attached to said plunger within said syringe.

16. A method of controlling an injector of the type having a motor which advances and retracts a plunger located within a syringe toward and away from a nozzle located at an end of the syringe to inject fluid into or out of an animal subject, adapted for use with syringe assemblies which have differing capacities, comprising:

detecting a physical indicia on a syringe installed on said injector, said indicia being related to the end of travel position of a ram moved by said motor when said syringe is mounted to the injector, and generating an electrical signal representative of said physical indicia,

causing said motor to move,

tracking the location of said motor while moving said motor, and

determining that a ram moved by said motor has arrived at its end of travel position, using said electrical signal and the tracked location of said motor.

17. The method of claim 16 further comprising:

ceasing motion of said plunger when said ram reaches its end of travel position.

18. The method of claim 16 wherein said electrical signal represents the length of an extender which is attached to said plunger.

19. An injector and syringe, comprising

a syringe having a plunger, a nozzle located in the front of said syringe, and physical indicia related to the range of travel of an injector ram coupled to the plunger when the syringe is coupled to an injector,

a motor in the injector which advances and retracts a ram coupled to the plunger located within the syringe toward and away from the nozzle of the syringe to inject fluid into or out of an animal subject, and

a controller in the injector adapted for use with syringe assemblies which have differing capacities, comprising:

a detector located proximate to the syringe when installed on said injector for detecting the physical indicia on said syringe, and generating an electrical signal representative of said physical indicia, and

a control circuit which causes said motor to move and tracks the location of said motor while moving said motor, wherein said control circuit computes the range of travel of said ram moved by said motor, using said electrical signal.

20. The injector of claim 19 wherein said control circuit ceases motion of said motor and plunger when the ram has reached and end of its computed range of travel.

21. The injector of claim 19 wherein said electrical signal represents the length of an extender which is attached to said plunger within said syringe.

22. A method of controlling an injector of the type having a motor which advances and retracts a plunger located within a syringe toward and away from a nozzle located at an end of the syringe to inject fluid into or out of an animal subject, adapted for use with syringe assemblies which have differing capacities, comprising:

detecting a physical indicia on a syringe installed on said injector, said indicia being related to the range of travel of a ram moved by said motor when said syringe is mounted to the injector, and generating an electrical signal representative of said physical indicia,

causing said motor to move,

tracking the location of said motor while moving said motor, and

computing the range of travel of a ram moved by said motor, using said electrical signal and the tracked location of said motor.

23. The method of claim 22 further comprising:

ceasing motion of said plunger when said ram reaches and end of its range of travel.

24. The method of claim 22 wherein said electrical signal represents the length of an extender which is attached to said plunger.

25. An injector and syringe, comprising

a syringe having a plunger, a nozzle located in the front of the syringe, and physical indicia,

a motor which advances and retracts the plunger within the syringe toward and away from the nozzle to inject fluid into or out of an animal subject, and

a controller comprising

a control circuit which causes the motor to move and tracks the location of the motor while moving the motor, and

a memory storing an offset value which is related to the capacity of said syringe,

wherein the control circuit is operable obtain an offset value from physical indicia detected on the syringe, and the control circuit computes a value indicative of the location of said plunger within said syringe by applying the stored offset value to the tracked location of said motor, and ceases motion of said plunger when said computed value indicates that said plunger is at an end of said syringe.

26. The injector of claim 25 wherein said offset value represents the length of an extender which is attached to said plunger within said syringe.

27. A method of controlling an injector of the type having a motor which advances and retracts a plunger within a syringe toward and away from a nozzle located in the front of the syringe to inject fluid into or out of an animal subject, comprising

causing the motor to move and tracking the location of the motor while moving the motor,

detecting a physical indicia on a syringe installed on said injector, said indicia being related to the capacity of said syringe, to obtain an offset value,

computing a value indicative of the location of said plunger within said syringe by applying the stored offset value to the tracked location of said motor, and

ceasing motion of said plunger when said computed value indicates that said plunger is at an end of said syringe.

28. The method of claim 27 wherein said offset value represents the length of an extender which is attached to said plunger within said syringe.

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